



PROTECTOR

Biodiversity

NATIONAL LAWS REGULATING ACCESS TO
GENETIC RESOURCES IN THE AMERICAS

EDITED BY SUSAN PERKOFF BASS • MANUEL RUIZ MULLER

FOREWORD BY MOHAMED L. ASHRY

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Edited by
Susan Perkoff Bass and
Manuel Ruiz Muller

Foreword by
Mohamed L. Ashry

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Foreword

As we approach the 21st century, the biodiversity challenge remains the same — to avert the sixth greatest extinction in the Earth's history — but the efforts to address it continue to evolve.

The old argument that biodiversity doesn't pay is giving way to the realization that biodiversity is the "natural capital" underpinning our \$30 trillion global economy. As the lucrative field of biotechnology expands, it continues to rely on compounds found in some of the Earth's oldest species. And nowhere is the value of diversity more closely linked to human welfare than in agriculture, where decreasing diversity stands as a major impediment to sustainability and food security. Biologically diverse ecosystems, such as tropical rain forests and coral reefs, are the world's most valuable source of natural products, at both the global and community levels, and these products often represent significantly higher financial returns over the long term than those of short-term exploitation and degradation of resources.

The three mutually reinforcing objectives of the Convention on Biological Diversity (CBD) — conservation, sustainable use, and equitable sharing of benefits from biodiversity — constitute the new standard for successful environmental practices. If it is to be feasible to protect the remaining stock of biological diversity, we must

collectively focus on policies to promote conservation and sustainable use and thereby ensure that all societies can develop without destroying the natural systems on which their prosperity depends. *Protecting Biodiversity* is an important contribution to this objective.

As the CBD's interim financial mechanism, the Global Environment Facility is pleased to have joined with the Environmental Law Institute, the World Bank, the International Development Research Centre of Canada, the John D. and Catherine T. MacArthur Foundation, and the Tinker Foundation in supporting this project.

Mohamed L. Ashry

CEO and Chair

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Preface

Access to genetic resources has, without doubt, become a central issue in discussions of the implementation of the Convention on Biological Diversity (CBD). Not surprisingly, since the CBD entered into force in December 1993 national efforts to develop access policies and regulations have been rapidly increasing, especially among countries rich in biodiversity. The project, Protecting the Biodiversity of the Americas, was launched to provide an overview of the current legal context for access to genetic resources in the Americas for those engaged in national efforts to develop policies, laws, and regulations.

The institutions participating at various stages of this project were Fundación Ambiente y Recursos Naturales (FARN, environmental and natural resources foundation), from Argentina; the Centre for International Environmental Law and Policy, from Canada; Fundación para la Defensa del Interés Público (foundation for defence of public interests), from Colombia; Estudios de Estructura y Administración del Estado (ESTADE, studies of the structure and administration of the state), from Ecuador; Asociación de Abogados Ambientalistas (AAA, association of environmentalist professionals), from Paraguay; Sociedad Peruana de Derecho Ambiental (SPDA, Peruvian society for environmental rights), from Peru; the Environmental Law Institute

(ELI), from the United States; and the Environmental Law Center of the International Union for the Conservation of Nature and Natural Resources (IUCN). The AMBIO Foundation (Fundación AMBIO), from Costa Rica, later joined the project and submitted a national study.

The idea for the project was introduced at a consultative meeting on effective implementation of the CBD, held in 1994 in Buenos Aires, on the occasion of the IUCN General Assembly. This meeting was hosted by FARN, with support from the World Bank and the Global Environment Facility.

The project was divided into three distinct phases. The first was the development of a common research methodology for the participating institutions to use in preparing country-specific studies, which was developed at a meeting of ESTADE in 1996, in Quito, Ecuador. The second phase involved conducting the research and preparing the national case studies. The studies were prepared throughout 1996 and early 1997. The information obtained in these studies was subsequently reviewed and formatted in a comparative chart produced by SPDA. The third and final phase was a workshop held in May 1997, in Cuzco, Peru. The participants at this workshop identified common trends in national policies and options for policy-makers in developing national access policies, laws, and regulations.

A parallel objective of this study was to strengthen the technical capacity of the project partners to conduct research and analysis and develop laws and policies on issues of access to genetic resources, as well as strengthening the project partners' ability to conduct effective educational and outreach activities. Two outreach meetings enabled the participants to exchange information and engage other partners in discussion. The first of these was held in Ontario in October 1997. The second was a conference held at the Universidad Nacional de Asunción (national university of the Assumption) in Paraguay, in May 1998. The latter was sponsored by AAA, ELI, and the Universidad Nacional de Asunción.

The United States is included in this study, although the CBD is not yet in force there, as it has yet to be ratified by the US Senate. Nevertheless, it is useful for several reasons to determine how existing US laws can be used to implement the portions of the CBD dealing with access and compensation for the use of genetic resources, as well as gaps or conflicts in the laws affecting implementation.

Moreover, the US case study is useful in comparing the Common Law regulatory system used in Canada and the United States and the systems of civil law used in most other countries in the Americas.

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Numerous organizations and persons have helped to design this project, conduct the research, and provide the necessary technical and financial assistance.

We would especially like to thank the Global Environment Facility for its support of, not only the 1994 meeting of the International Union for the Conservation of Nature and Natural Resources (IUCN), where the broad concept for this project was developed, but also the meeting in Quito, where the groups established the research methodology; the information exchange workshop in Paraguay; and, finally, the publication of this report. The International Development Research Centre (IDRC) of Canada gave support to prepare the national case studies of Canada and Peru, the comparative chart, and the workshop on access to genetic resources held in Urubamba, Peru, and provided substantial support for this publication. We also extend our gratitude to the John D. and Catherine T. MacArthur Foundation and the Tinker Foundation for providing support for the national case studies and this publication. The Environmental Law Center of IUCN helped to provide project participants with background on the international framework for access to genetic resources.

In addition, numerous people contributed to each of the national case studies. The Argentinean project staff comprised Dolores Lavalle

Cobo, Hernán López, Marta B. Rovere, and Juan Rodrigo Walsh. The Canadian staff and volunteers of the Centre for International Environmental Law and Policy who worked on this project were Karen Clark, Ian Attridge, Risa Schwartz, Colin Jones, Rhiannon Davies, Jan Rabantek, Nancy Palardy, and Nadya Tymochenko. Reviewers of the Canadian case study included Brad Fraleigh, Howard Mann, Michelle Swenarchuk, Linda Nowlan, Laurie Henderson, Alex Mosseler, David Brooks, James (*sa'ke'*) Youngblood Henderson, David VanderzWaag, and Yves Couriveau. In Colombia, John Ivan Nova Arias, Claudia Mora, and Andrea Padilla Munoz contributed to the project. The Costa Rican project director was Jorge Cabrera. In Paraguay, the project staff comprised Gustavo Laterza Rivarola and Soledad Villagra de Biederman. From Sociedad Peruana de Derecho Ambiental (Peruvian society for environmental rights), the project staff comprised Jorge Caillaux, Manuel Ruiz, and Rosario Tamashiro. The US project staff from the Environmental Law Institute comprised Martha Aldana, Susan Bass, Nancy Golubiewski, Jessica Jacoby, James McElfish, Sergio Mujica, Byron Swift, and Jill van Berg.

Chapter 1

Introduction

General overview

The issues of how and under what conditions genetic resources can be accessed and subsequently used, particularly for industrial or commercial purposes, have become central topics of discussion among national and international policymakers over the past few years, particularly during the negotiation and implementation processes of the Convention on Biological Diversity (CBD), which was signed on 5 June 1992.

It is widely recognized that genetic resources and biologically derived materials in general are fundamental to the production and generation of seed varieties, medicines, and a wide variety of industrial products. Access to these resources and materials is also becoming increasingly important in the field of biotechnology. Although the economic importance of genetic resources is now widely recognized, specific data on the subject are scarce or, in the best of cases, difficult to obtain. As the key to the future biological diversity of the

planet, moreover, genetic resources also have important cultural, spiritual, and aesthetic values.

The mostly unregulated international flow and exchange of genetic resources and biologically derived materials can be traced through several centuries. Only recently has the regulation of the transfer of these resources become a major concern and a converging point of discussion in national and international forums.

In most cases, the "biodiversity-rich" countries are also developing countries, and the "biodiversity-poor" countries are those highly industrialized countries with powerful biotechnology sectors. It is therefore not surprising that, following an increasing and more obvious demand for biological resources, the need to control or maintain their free flow has structured and polarized political positions.

Although biodiversity-rich and biodiversity-poor countries can alike implement access controls and regulatory mechanisms, there is reason to be cautious about unduly restricting the flow of resources. Genetic resources are fundamental to the basic research conducted in a number of fields. The distinction between basic and applied research appears, at the very least, blurred in the context of genetic resources. Most often, basic research leads at some point to commercial or industrial research and development. But the difficulty drawing the line in this area complicates policymaking on the issues of access and compensation.

The first international and intergovernmental discussions on access to genetic resources began in the 1980s in the forums of the United Nations Food and Agriculture Organization (FAO), specifically during the negotiations on implementing the International Undertaking on Plant Genetic Resources (the Undertaking). The Undertaking addresses the issue of genetic resources as they relate to food and agriculture. Although nonbinding, the Undertaking establishes the principle that plant genetic resources are the "heritage of mankind and consequently should be available without restriction" (FAO n.d., article 1). Developed countries became concerned that this principle might be applied to plant breeders' varieties, which are potentially subject to intellectual property rights (IPR). In their opinion, "heritage of mankind" should under no conditions include plant breeders' varieties.

Subsequently, the Undertaking was clarified through various annexes stating more precisely that the Undertaking is not opposed

to the plant breeders' systems of rights and that "free access" does not imply "free of charge" (Annex I, Resolution 4/89, 1989). The annexes include a broad reference to farmer's rights (Annex II, Resolution 5/89, 1989) and elucidate the compatibility of the Undertaking with the concept of sovereign rights over plant genetic resources (Annex III 3/91, 1991).

A few years later, in 1987, the first attempts were made to promote the development of an international convention on biological diversity. During the negotiation of the CBD, which was originally conceived as a framework for an international conservation treaty, new issues fueled intense intergovernmental and nongovernmental debate. These issues included the question of access to genetic resources (not limited to plant genetic resources for food and agriculture) and the sharing of benefits from their use; technology transfer; IPR, a highly controversial issue, which at the time was also under discussion in the General Agreement on Tariffs and Trade (GATT) and is currently under discussion in the World Trade Organization (WTO); indigenous peoples' knowledge of biodiversity; and biosafety.

Specifically in article 15 ("Access to Genetic Resources"), the CBD sets up a new international regime for regulating access and use of genetic resources. It recognizes the standing principle that states have sovereign rights over their natural resources and thus the authority to determine the conditions of access to their national genetic resources (article 15 [1]). As well, it requires that conditions be established to facilitate this access (article 15 [2]). Other requirements are that benefits derived from the use of these resources are fairly and equitably shared (article 1) and that access is granted under mutually agreed terms (article 15 [4]) and subject to prior informed consent (article 15 [5]).

There is an intricate international policy and regulatory context for these issues, which includes the complex relations of the FAO, CBD, and WTO. Clear lines are drawn between countries favouring a strictly regulated control of genetic resources and those suggesting that flexibility and limited control in access flows are the keys to promoting conservation and sustainable use (the ultimate goals of the CBD). For the most part, these positions align themselves, respectively, with those of the biodiversity-rich and biodiversity-poor countries. The latter depend on the former to continue their research and

development processes and provide their *ex situ* facilities with new materials and resources. Increasingly, Southern countries take defensive stances, and they are also legitimately concerned about current restrictive developments in IPR regimes worldwide. Through these regimes, transnational corporations are "legally" monopolizing the control and use of biologically derived materials, specifically through product or process patents or plant breeders' rights. The activities associated with the extraction of the resources for these materials and the economic control gained through patents and plant breeders' rights may have potentially damaging cultural and commercial consequences for these countries. Northern countries, in contrast, increasingly work to strengthen their IPR regimes while resisting undue restrictions on access.

Within this context, one thing becomes certain: all sides consider the flows of genetic resources and biologically derived materials — whether strictly regulated or under more flexible control — necessary for the continued benefit of humankind. Reaching a balanced and equitable agreement, however, with effective implementation of CBD guiding principles, will be a long-term and difficult project.

National access regimes and efforts

The highly convoluted and political debates about CBD article 15 ("Access to Technology"), article 16 ("Transfer of Technology"), and article 19 ("Handling of Biotechnology and Distribution of its Benefits") have catalyzed national efforts to develop access policies and legislation. This is especially true in biodiversity-rich countries, where most bioprospecting has traditionally taken place. Five or six years ago, only a few experts and governmental agencies were engaged in the dialogue on this issue. At present, genetic resources and related issues occupy important places in the political agendas of many countries. Some countries have decided to adopt laws on access pursuant to more general biodiversity or natural-resource laws, whereas others are addressing the issue with specific access legislation. Some examples of these laws are given below:

- The *National Environment Management Act*, Law 13/94 of the Gambia, empowers the government to limit, restrict, or

control the commercialization of any component of biological diversity. Furthermore, under article 35 of this Act, the Council may adopt regulations prescribing guidelines on access to genetic resources, specifically "a) measures regulating the export of germplasm; b) measures for the sharing of benefits derived from germplasm originating from the Gambia; and c) fees to be paid for access to germplasm."

- On 2 September 1996, Ecuador enacted a "Law which Protects the Biodiversity of Ecuador." This law establishes the state's property rights over species, as well as its obligation to develop regulations on the exploitation of species and their genetic resources, with due respect to indigenous peoples' rights over their knowledge of biodiversity and the genetic resources found in their territories.
- The Philippines opted to act through specific legislation. On 18 May 1995, it adopted Executive Order 247, "Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources in the Philippines, their By-Products and Derivatives for Scientific and Commercial Purposes and for other Purposes." On 2 June 1996, the Department of the Environment and Natural Resources issued Administrative Order No. 96-20, "Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources." These laws address the issues of who is authorized to access the country's biological and genetic resources and under what conditions.
- Bolivia, Colombia, Ecuador, Peru, and Venezuela — through their membership in the Andean Pact (an economic and social-integration treaty) — adopted Decision 391 on a "Common Regime on Access to Genetic Resources." This entered into force in mid-1996. It sets minimum common rules on access and includes provisions on such relevant aspects as indigenous peoples' knowledge, IPR, and technology transfer. Andean Pact decisions are automatically in force in all signatory countries once these decisions are published in the Pact's official gazette and need no further approval from national legislatures.

- Numerous other countries (including Australia, Brazil, Cameroon, Eritrea, and Fiji) have also adopted or are in the process of developing laws on access to genetic resources. A common feature of most of these draft laws and regulations is a set of control measures and the state's active role in the regulatory process to grant or authorize access.

Although these examples show that a new international system is rapidly developing for the regulation of the flow of genetic resources and biologically derived materials, critical issues still need to be addressed to enable this development to proceed constructively. First, concerns are surfacing within the scientific community about the issue of how access systems will impact on research and development. Second, there is the question of the ability of general-framework laws, or even the CBD's principles themselves (that is, confidence building, cooperative North-South processes, and case-by-case arrangements), to efficiently and cost-effectively serve the CBD's objectives while fairly and equitably accounting for the interests of all parties.

The project

The Protecting the Biodiversity of the Americas project is a multiyear research endeavour, with support from the World Bank, the Global Environment Facility, the International Development Research Centre, the John D. and Catherine T. MacArthur Foundation, and the Tinker Foundation. The project has sought to analyze the current laws, policies, and regulations on access to genetic resources within the broader context of conservation and sustainable use in seven countries: Argentina, Canada, Colombia, Costa Rica, Paraguay, Peru, and the United States.

The project has provided a comprehensive analysis and comparative overview of these national laws and policies. An important result of the project has been the elucidation of the differences between the underlying conceptual principles separating Canadian and US policies on access from Latin American approaches to the subject. The former recognize and in some cases promote the notion of private-property rights over natural resources, whereas the latter consider state sovereignty over natural resources the defining factor

in the design of access-related regulatory mechanisms. Information is provided to enhance ongoing dialogue on access issues and enable policymakers, the private sector, and indigenous peoples' organizations, among others, to understand the current status of these policies and laws in the Americas.

Chapter 2 presents a brief summary of the state of each country's laws, policies, and regulations on access to genetic resources, either from *in situ* or *ex situ* sources.

Chapter 3 presents a set of comprehensive tables that identify specific commonalities and differences among the participating countries. The tables provide an overview of how each country deals with a broad range of issues. As most laws on access fall into the context of conservation and sustainable-use legislation, appropriate references to these broader forms of legislation are made.

Chapter 4 includes the options, conclusions, and recommendations identified during a 3-day workshop on access, attended by representatives from the Centre for International Environmental Law and Policy, the Environmental Law Institute, AMBIO Foundation (Fundación AMBIO), Fundación para la Defensa del Interés Público (foundation for the defence of public interests), Asociación de Abogados Ambiental (association of environmentalist professionals), and Sociedad Peruana del Derecho Ambiental (Peruvian society for environmental rights) in Urubamba, Peru, in May 1997. These options, conclusions, and recommendations highlight the issues that the participating organizations believe are fundamental to the process of developing national laws and policies on access to genetic resources. These ideas are not intended to be absolute or definitive views on the needs in this arena but to provide topics for consideration and alternatives for analysis in the development and implementation of national access legislation.

Access laws and policies are currently at an interesting crossroads worldwide. As more and more efforts are made to regulate access to genetic resources and to establish benefit-sharing mechanisms, the difficulties that basic science, particularly research, is facing in the medium term become increasingly clear. Change seems inevitable, and the scientific community will need to adapt to the new CBD rules. However, there are ways to facilitate a more harmonious development of laws and policies.

Scientists, especially those engaged in pure science, must become more involved in the debates and discussions of the access and benefit-sharing issues. Whereas the private sector is already well involved in presenting its views and protecting its activities and interests, there is an urgent need to hear the voices of the taxonomist, the biologist, the herbarium keeper, the botanical garden director, the university professor, and others not directly linked to the "for-profit" sector — whom the access and benefit-sharing provisions of the CBD were originally designed to benefit. Bringing all the concerned voices into the dialogue is necessary to ensure that policymakers receive sufficient input into their decision-making processes and have an understanding of the implications of their decisions.

Chapter 2

Seven Country Reports

Argentina

In 1994, Argentina ratified the CBD, through Law 24.375. In the same year, it promulgated a new Constitution, based on the changes introduced by the Santa Fe Constituent Convention. Article 41 of the Constitution incorporates a new "environmental right," by establishing that "the authorities will care for the protecting of this right, the rational use of natural resources, the preservation of natural and cultural patrimony and of biological diversity."

Since the creation of Argentina's first National Park at the beginning of the century, its judicial system has been concerned about the protection of ecosystems and, in some cases, of species. However, making biological diversity a category of judicial protection is an innovation in the Argentine statutory system. This innovation will doubtless lead to an effort to harmonize the current judicial and institutional systems with the commitments and obligations of the CBD. Several commitments emanating from the

CBD will require Argentina to adopt policies, rather than self-executing rules or concrete obligations. This is true, for example, of the commitments to international cooperation on science and technology. Enforcement of these commitments will require more detailed policy tools.

Several projects have been developed to identify the judicial and institutional needs in the implementation of the CBD in Argentina. The work of Fundación Ambiente y Recursos Naturales (environmental and natural resources foundation), pursuant to the Protecting the Biodiversity of the Americas project, is an example of a project developed for, among other purposes, the analysis of national policy and legal and institutional needs regarding access to genetic resources.

Another project to define public policies needed to effectively protect biological diversity is to elaborate a national strategy compatible with the guidelines in article 6 of the CBD. The CBD demands the development of such public policies for the conservation of biological diversity, sustainable use of its components, and the equitable distribution of the benefits derived from access and use of those resources. The elaboration of a national strategy and its action plans are the means by which the parties to the CBD translate its guidelines and general principles into action and concrete policy measures.

The main challenge in implementing the CBD in Argentina is to articulate and distribute responsibilities among the three levels of government (federal, provincial, and municipal). Article 41 of the Constitution gives the federal government the duty of overseeing the protection of biological diversity, as part of its responsibility for establishing the basic (or minimum) guidelines for environmental protection. The provinces can supplement these guidelines, as long as the "minimum or threshold guidelines" set up to implement the protection of biodiversity do not alter (or conflict with) local jurisdiction. In other words, the federal government (that is, Congress) is entitled to set up threshold standards, which more stringent local environmental legislation may supplement. In addition, under a certain interpretation, the power to enforce federal legislation lies with the provincial courts. Article 124 of the Argentine Constitution supports this interpretation by establishing the principle of the provinces' authority over their natural resources and thus the authority to regulate the use, development, and conservation of these resources.

The Constitution assigns the authority to regulate property rights, in accordance with the *Civil Code* of Argentina, to the national Congress. The *Civil Code* defines all substantive issues of civil or commercial law, such as the means of acquiring or extinguishing property rights. It is a prerogative of Congress to enact amendments to property law required by international agreements. The power to regulate civil law, and hence property rights, in the public interest is known as "police power," as in the United States. Both federal and provincial authorities may execute laws in the public interest.

Argentine civil laws ensure property rights over animals, but not those to genetic resources. The Roman legal tradition has not developed to the point of including genetic resources within the concept of property rights. Conceptually, the legal status of genetic resources would be the same as that of the biological resources (plants or animals) that carry them.

Similar provisions are in place regarding forestry fauna and resources. These are in the jurisdiction of the states and are regulated by state rules. Administrative procedures and permits indirectly regulate who can access these resources and how they may use them.

The Trade Related Aspects of Intellectual Property Rights modified the Argentinean patent law (Law 111), which determines that

- Patents shall be awarded to inventions (products or processes in all fields of technology);
- Inventions can be excluded from patentability if their exploitation might be contrary to the public order or morality, negatively impact on human, animal, or plant life, or health, or seriously prejudice the environment;
- Plants and animals (other than microorganisms) and processes essential to the production of plants and animals (other than nonbiological or microbiological processes) can also be excluded from patentability; and
- Protection of plant varieties must be provided through patents, an effective *sui generis* system, or a combination thereof.

Like other countries in the region, Argentina has no specific legal mechanisms to protect traditional knowledge. However, the Constitution (article 75 [17]) acknowledges the preexistence of

indigenous tribes within Argentinean territory. At present, these tribes' materials and intellectual property are under no specific protection and therefore subject to the property rules of the *Civil Code*.

As for *in situ* and *ex situ* conservation, the survey done in Argentina differentiates between the federal and provincial legal systems. The need to articulate a policy for *in situ* conservation became apparent in the process of elaborating the Argentinean National Strategy for the Protection of Biodiversity. Specific issues related to *in situ* conservation needed to be addressed: How would the new policy relate to the traditional framework for protected areas? How would the new policy promote the creation of representative systems to allow preservation of biological diversity on private properties dedicated to productive activities? In addition, one of Argentina's weaknesses may be that it insufficiently protects aquatic and maritime ecosystems, despite the fact that these resources are regulated by several international agreements to which Argentina is a signatory, such as the Ramsar Convention.

The research and institutional capacities in Argentina, particularly in the farming and food industries, leave the country to face problems similar to those of other developing countries (that is, the need for access rules and policies). However, Argentina also has advantages similar to those of developed countries (that is, capacities to benefit from IPR protection and share research results and technology).

Doubtless the implementation of the CBD in Argentina will involve the complicated task of adapting current rules to ensure appropriate enforcement of the CBD's objectives within the scope of domestic legislation. In particular, it will be important to develop systems to allow the preservation of biological diversity *in situ* and legal mechanisms to allow the distribution of benefits derived from research and development of genetic resources.

Canada

The Canadian case study provides detailed descriptions of the laws and policies in Canada on access and compensation for genetic resources. The emphasis in Canada is on the conservation of habitat and species-level genetic resources, with few clearly stated laws or policies dealing with access or sharing of benefits from access or use of *in situ* genetic resources. The one exception to this general state of

affairs is the federal policy on access to *ex situ* genetic resources in federal and provincial gene and clone banks. This policy provides unrestricted access to these genetic resources for *bona fide* researchers and plant breeders.

Possibly as a result of the highly developed state of Canada's *ex situ* collections, the case study also observed that there appears to be very little *in situ* bioprospecting in Canada. As noted by one government spokesperson interviewed for the case study, people looking for the best genetic resources in Canada do not need to "root around in the wild." One can bioprospect in a lab coat in Canada.

Although Canada has many conservation laws at the federal and provincial levels dealing with protection of habitat, animal species, and plant species, they are not entirely adequate to protect Canada's biodiversity. Moreover, resource-management laws and policies in agriculture, forestry, mining, and other extractive industries sanction activities highly destructive of biodiversity. The case study noted that Canada has not yet achieved a balance between conserving and exploiting its natural resources, including its *in situ* genetic resources.

Another important finding of the case study was that there appear to be gaps in Canadian law and policy regarding genetic resources, particularly concerning the rights of private property owners and Aboriginal peoples. The presumption implicit in current federal policies is that private property owners are free to control access to the genetic resources on their property and to contract with those seeking access to them to share in the benefits. The case study proposed that the laws are actually not quite that clear. In particular, the assumption that an individual owns every component of every living thing on his or her property is thrown into some doubt by plant breeders' rights in Canada, which ascribe ownership of genetic materials in plants in accordance with plant breeders' rights, and by the presumptions of the sale of animal sperm and ova, which disallow ownership of the genetic materials in these commodities. The case study concluded that the question of private ownership of *in situ* genetic resources has yet to be settled in Canada.

Another unsettled, much more difficult, issue is that of the Aboriginal peoples' rights to control access to *in situ* genetic resources on Aboriginal lands. The difficulty arises from the broad range of legal rights accorded to Aboriginal peoples in Canada, with some Aboriginal

peoples entitled to treaty rights, some not. In addition, some are in a position to benefit from Canada's land-claims process, others not. The case study noted that if the issue is to be addressed (and so far it has not), Aboriginal peoples with rights under the land-claims process might be in the best position to negotiate for control over access to genetic resources on their lands. Regarding the other two main areas of Aboriginal legal rights — treaty rights and aboriginal rights — so far no court has considered the question. The issue of the rights of private property owners will also not be settled until a court considers it or the government passes legislation.

It was not the purpose of the Canadian case study to critically evaluate federal or provincial compliance with the CBD. A number of reports have dealt with Canada's efforts to conserve its biodiversity (see, for example, Attridge [1996] and WWF Canada [1996]).

One problematic issue does arise, however, from the findings of the Canadian case study. As noted above, Canada has few laws or policies expressly dealing with *in situ* genetic resources and has an open-access policy concerning *ex situ* genetic resources. This state of affairs appears to suit Canada's domestic interests — the research turned up no expression of discontent or disfavour regarding the status quo. In other words, bioprospecting, *in situ* or *ex situ*, is a nonissue in Canada. Although Canadian policy appears unproblematic domestically, it may create problems if it is imposed on other countries. Implicit in the Canadian open-access policy (and this was expressly stated by a spokesperson for the federal government) is the understanding that all countries should provide open access to their *in situ* as well as their *ex situ* genetic resources. This understanding, along with the implicit threat of some form of retaliation against other countries seeking to control access to their genetic resources, frustrates the intentions of the CBD.

Schrecker (1997) commented that countries holding lands in reserve to conserve biodiversity bear a cost in that they are unable to make other uses of these protected lands, such as mining and forestry. Schrecker also suggested that if a country is not rewarded for preserving its lands — such as through fees for access, royalties from use, or technology transfer — then the burden of its conservation efforts is not shared. If the burden is not shared, then the pressure to turn the land to other productive uses increases, and the likely result is the eventual development of the land and loss of biodiversity. A recent example of just this sort of transfer of conserved land

to a productive use occurred in Canada in December 1996. The Government of Nova Scotia announced that the Jim Campbell barren, a natural area covering 1 700 ha, had been opened to mining exploration about a year after the government's announcement that it would include this area under the national ecosystem-protection program. Shrecker's (1997) reasoning reflects an accurate interpretation of the CBD, which states as one of its objectives the fair and equitable sharing of benefits arising from use of genetic resources. Canada's apparent insistence that all countries permit open access to their *in situ* genetic resources ignores this objective.

Canada's assumptions regarding other countries' obligations to provide open access to their *in situ* and *ex situ* genetic resources possibly arises from its own emphasis on *ex situ* genetic resources, which are the materials of primary interest to researchers. Canada's policy conflates *in situ* and *ex situ* genetic resources and applies the plant breeders' worldwide tradition of permitting open access to *ex situ* plant genetic resources to all genetic resources everywhere. This conflation is an error in Canadian policy. It is counterproductive, as well as contrary to the intentions of the CBD, to impose Canada's access policy concerning its *ex situ* genetic resources on other countries in regard to *in situ* genetic resources. This is, however, an easy error to correct. Canada may keep its internal policies absolutely intact. It needs only to acknowledge its obligation to the international community to assist countries seeking to protect their *in situ* biodiversity and share the responsibilities, financial and otherwise, borne by those countries.

Canada may also benefit domestically by openly acknowledging that conservation costs Northern countries as well. If it turns its attention to questions of how Canada can prosper from preserving biodiversity *in situ*, perhaps other protected areas in Canada can avoid the fate of the Jim Campbell barren.

Colombia

Legal regime for genetic resources

The Colombian Constitution establishes three types of property: private, state, and public. It also recognizes the social function of each type of property, including an ecological function. The owner of

private property can be an individual (natural or legal citizen) (article 58) or a collective entity (such as in the case of land belonging to indigenous or black communities) (article 329). The Constitution determines the state's goods, which include Colombia's underground and nonrenewable natural resources (article 332), the territorial sea, the contiguous zone, the outer continental shelf, the exclusive economic zone, aerial space, a segment of the geostationary orbit, the electromagnetic spectrum (article 102), and those goods the state owns as private property, subject to the same conditions as individuals' private lands (article 58). Public-use goods are determined not by their ownership, but by their effect on the public domain in terms of the national cultural richness, public use, and public space (articles 1, 63, 82, and 102).

After the Constitution, the main environmental norms in Colombia are the *Natural Resources Code* (NRC) (Decree 2811, 1974) and Law 99 (1993). The NRC protects renewable natural resources. Law 99 has improved the institutional structure related to management and conservation of Colombia's environment and natural resources.

Terrestrial and aquatic areas

Public areas — The NRC established the basis for environmental protection in Colombia. Complemented by later legislation, this code regulates nonmaritime waters (Decree 1541 of 1978), the sea and seabed (Decrees 1875, 1876, and 1877 of 1979), terrestrial flora (wild flora and forests), terrestrial wildlife and hunting (Decree 1608 of 1978), and hydrobiological resources (Decree 1681 of 1978).

The current laws on protected areas and National Parks are of particular importance to the question of access to genetic resources in Colombia. In terms of environmental protection, these laws promote a better understanding of genetic resources through research administered by the responsible authority. The National Parks System comprises national parks, natural reserves, unique natural areas, flora sanctuaries, wildlife sanctuaries, and park routes (Decree 2811, article 329). Decree 622 (1977) established the various "zones" of use and management of resources within these protected areas. These include the Intangible Zone, the Primitive Zone, the Natural Recovery Zone, the Historic-cultural Zone, the Exterior General Recreation Zone, the High Density of Use Zone, and the Buffer Zone.

Private areas — The second book of the Colombian *Civil Code* regulates the dominion, ownership, use, and enjoyment of goods. Article 669 of this Code defines property. The Constitutional Court, in its judgment C-006 of 18 January 1993, held that property rights are a concrete aspect of citizens' constitutionally guaranteed liberties, as long as the exercise of those rights complies with the law and does not infringe on others' individual rights. This judgment made clear that property owners are sovereign and have the right to exercise the maximum power over their property, as conceived in law. Access to genetic resources is thus governed by property laws, as owners have control over all plants and animals on their property.

Local and indigenous communities — Articles 329 and 330 of the Colombian Constitution of 1991 created a special regime for indigenous territories, allowing them to govern themselves through their own councils, which they form and regulate according to indigenous uses and customs. One of the functions of these councils is to look after the preservation of the natural resources in the territories.

In Decree 2164 (1995), Colombia defined indigenous territories as areas an indigenous community regularly or permanently possesses in accordance with Law 21 (1991). Through this law, Colombia approved Convention 169 of the International Labour Organization on Indigenous and Tribal Peoples, the *Mining Code* of 1988, and Decree 2164 (1995). However, this collective property right is not absolute. The autonomy of the indigenous authorities in the management of their own affairs, especially regarding the use of natural resources (Constitution, article 330), must be exercised with "full responsibility" (Constitution, article 95[1]).

Black communities — Article 63 of the Colombian Constitution mentions the communal lands of ethnic groups and establishes a special protection for black communities. Article 4 of Law 70 (1993) recognizes the collective property rights of black communities. The lands of these communities are inalienable, cannot be transferred to any other entity (even if that entity has possessed the land "in good faith"), or made subject to any liens. This collective property right is exercised according to its social function, which includes an inherent ecological function.

Marine areas

Law 10 (1978) is the Colombian domestic legislation regulating maritime issues. Through this law, the Colombian government has established the extension of its territorial sea and the nation's rights over the outer continental shelf and exclusive economic zone. Decrees 1874, 1875, and 1876 (1979) established the Coastguard Corps, norms on pollution prevention in the marine environment, and measures regarding conservation and use of marine natural resources. In addition, through Law 12 (1992), Colombia approved the Protocol for the Conservation and Administration of Marine and Coastal Protected Areas of the Pacific Southeast.

***Ex situ* collections**

The Ministry of Environment in Colombia is responsible for the research, use, and management of the genetic resources of Colombia's fauna and flora. The ministry has accomplished this objective with the support of the Institute of Biological Resources Research (the Alexander Von Humboldt Institute), created by Law 99 (1993). The institute is in charge of carrying out basic and applied research on the genetic resources of national flora and fauna and oversees the creation of a scientific inventory of Colombia's biodiversity.

According to Law 99, the appropriate regulation of *ex situ* conservation must take into account the following: the species to be conserved, origin of the specimen taken for conservation, and the environmental conditions under which the specimen was collected. Scientists must also apply the appropriate techniques to ensure that the collection represents the genetic variability of the species in the collection.

Access to genetic resources

Decision 391 of the Cartagena Agreement Commission (of 1996) established the laws on access to genetic resources in Colombia. It is important to emphasize that this decision grants sovereignty to each member country over its genetic resources and their by-products. The decision puts these resources under the patrimony of the nation, makes the nation's right to these resources inalienable and incapable of being transferred to any other entity, and gives citizens a very important role in monitoring and protecting these resources.

Permits

Article 81 of the Colombian Constitution establishes that the state must regulate the import, export, and use of genetic resources in the national interest. No regulatory scheme is at yet in place to grant permits for access to species and their genetic resources. However, articles 54–58 of the NRC may apply, as in general terms they regulate natural-resource permits. Decree 1608 (1978) regulates ownership and use of wildlife. Agreement 33 (1978) of the National Institute of Natural Resources regulates the ownership and use of fauna.

Bioprospecting

Very closely related to the issue of permits is that of bioprospecting. Communities and pharmaceutical companies or research centres often enter into bioprospecting agreements. But in Colombia, bioprospecting is not yet regulated. Nevertheless, it is considered a legal activity.

Distribution of benefits

There are several legal mechanisms governing the distribution of benefits from access to genetic resources: a decision under the Andean Pact that focuses on the Common Regime on Genetic Resources Access; articles 1, 3, 15, 16, 19, 20, and 21 of Law 165 (1994), which approved the CBD; Law 170 (1994), which approved the charter of the International Center of Genetic Engineering and Biotechnology, created in Madrid in 1983; and, finally, article 5, No. 8 of Law 99 (1993).

Technology transfer — The Ministry of Environment and the Alexander Von Humboldt Institute have a mission to develop national policy on biodiversity and thereby promote efforts to identify appropriate technologies for Colombia's continental, coastal, pelagic, and insular biodiversity. They are also creating the mechanisms needed to facilitate diverse research entities' access to technologies to facilitate the generation, validation, and dissemination of knowledge of biodiversity. Finally, they are encouraging research on the development and adaptation of technologies needed to transform current systems of production into ones that favour more sustainable use of biodiversity.

Measures for the conservation and sustainable use of genetic resources

Species protection

The Alexander Von Humboldt Institute is promoting the protection of species by strengthening and promoting genetic banks and biotechnology programs. Similarly, the International Cooperation and Legal offices of the Ministry of Environment are encouraging the enactment of a biosecurity protocol and national regulation to control the impacts of releasing exotic species or genetically modified varieties into Colombia's natural environment.

Environmental-impact assessment

Article 22 of Law 99 (1993) established environmental licences as instruments for making environmental planning decisions, as well as for defining appropriate measures to prevent, correct, compensate for, and mitigate environmental impacts and adverse effects of development projects.

Prohibitions and sanctions

Article 85 of Law 99 (1993) provides Colombia's environmental authorities with the authority to enforce policy measures and impose fines and sanctions established by the law.

Final comments

In Colombia, the Ministry of Environment is responsible for implementing the CBD, without prejudice to the authority of other entities, such as the Ministry of Interior and the Ministry of Defence. From the research on norms for implementing the CBD, it can be concluded that local laws prevail in several areas (wildlife, flora, and water resources, among others). In most cases, the currently applicable national norms are limited to the decisions of the Cartagena Agreement Commission, a fact that highlights the lack of specific national legislation on this issue.

Costa Rica

In terms of genetic and biochemical resources, one of the most important lessons learned from Costa Rican experience is the need to develop specific rules to govern access to these resources within a framework of public policies adequate to address as well the broader issues related to these resources.

Regulatory systems governing access are important and constitute the basis for moving forward in terms of further research, prospecting, and commercialization of genetic and biochemical resources in Costa Rica. However, by themselves, these systems are inadequate to achieve just and equitable distribution of the benefits of biological diversity and its conservation. Policymakers also need to properly understand national interests and priorities in the use of biological diversity and the access and transfer of technologies within existing bioindustrial markets. In addressing the need to incorporate access into national development agendas, legislation will certainly be needed. But alone, it will be insufficient to ensure compliance with the objectives of the CBD. The presence of appropriate rules for access to genetic and biochemical resources will hardly guarantee economic development in biodiversity-rich countries, unless those rules are linked to policies, strategies, and national alliances to aid in reaching these economic objectives. Understanding this need to incorporate the "big picture" will be necessary to developing successful strategies for the sustainable use of genetic resources and make it easier to define the role of national access regulations as tools for their sustainable use.

Although in the past Costa Rica lacked today's modern legal framework for access, diverse factors have contributed to its positive experiences with its efforts to comply with the CBD, including

- Its having a national strategy on conservation and sustainable use of natural resources;
- Its understanding of the access-to-resources concept as a mechanism to facilitate conservation of these resources;
- Its National System of Conservation Areas, which has, despite its problems, achieved relevant advances;

- ✱ Its having created institutions, such as the National Institute for Biodiversity, to give added value to Costa Rica's resources by facilitating technology transfer, capacity-building, etc.;
- ✱ Its understanding that its society must recognize the wealth of its biodiversity as essential to improving its quality of life if it is to succeed in conserving its resources;
- ✱ Its gradual acquisition of skills in negotiation and knowledge of biomarkets and bioindustries;
- ✱ Its government's commitment to supporting successful initiatives for sustainable use of genetic resources; and
- ✱ Its use of technology transfer.

These are some of the factors that have allowed Costa Rica to benefit from access to its resources.

Despite these advantages and benefits, some important problems might become obstacles to Costa Rica's implementation of a policy framework for access to genetic resources. For example, Costa Rica needs to strengthen the National System of Conservation Areas. The state's role in ensuring the territorial rights of indigenous populations needs to be clearly defined. There are also few regulations addressing access to *ex situ*, especially agricultural, resources. In addition, the need to form alliances of diverse sectors to realize the benefits of prospecting agreements is insufficiently appreciated in Costa Rica. A related issue is the lack of clarity on issues related to the marine environment and prospecting the biodiversity of marine ecosystems. Finally, Costa Ricans lack knowledge of the reality and nature of the market for bioprospecting and the format for certain sectors to negotiate agreements.

The government has attempted to solve some of these problems by enacting comprehensive legislation on biodiversity, with detailed regulations on access. The long process through which Costa Rica approved its biodiversity law (Law 7788 of May 1998) provided some additional lessons:

- ✱ The participation of the various sectors involved in the topic (universities, research institutes, nongovernmental organizations, the private sector, government, indigenous people,

farmers, etc.) is vital to considering the various interests affected by this type of law.

- The products of these processes and the agreements they generate are the result of extensive negotiations between parties with sometimes conflicting vested interests. As such, technical quality may need to be compromised in order to achieve valuable widespread participation.
- Implementing the legal framework for access in a controlling or restrictive manner runs the risk of severely affecting national research and development or making it inapplicable. A restrictive framework may take away the incentive for access and thus make it impossible to distribute the benefits.

This law establishes general considerations, such as objectives, the scope of application of the law, guiding principles, and the ownership regime for biological diversity, which is characteristic of a framework law. It also establishes criteria for interpretation and definitions, which are indispensable to giving appropriate value to its provisions. In addition, the law establishes a legal institutional structure to monitor and control access, called the National Commission for Management of Biodiversity, which has a technical office to support its day-to-day activities. The law gives a legal basis for the National System of Conservation Areas and provides the administration with a more participatory role. The law provides some norms on biosafety, conservation, and sustainable use of ecosystems and species. It also contains norms on IPR, *sui generis* community rights, education and public awareness, research, technology transfer, incentives, environmental-impact assessments, and procedures and sanctions.

With respect to access, the text of the newly enacted law is yet to be implemented. Nevertheless, in addition to the general points, mentioned above, about the formulation of the law, it is important to highlight some further aspects. The law clearly defines and includes within its scope the characteristics of goods derived from genetic and biochemical resources under public control. These goods are subject to a specific system of property rights.

Likewise, it specifies exceptions to the rules on access, such as human genetic materials and nonprofit exchanges among local communities and indigenous populations. In accordance with the CBD, the new legislation attempts to establish special procedures for

access, including requirements for requests, prior informed consent, and objections on cultural grounds. The law regulates the terms and conditions for distributing and obtaining permits for access and contains general rules on the distribution of benefits. It also establishes a public registry of access agreements and sets rules to guarantee the protection of confidential information. The law is a bit unclear regarding *ex situ* collections, as it only refers to the regulation governing access to these collections. This regulation is particularly important to the agricultural sector. It distinguishes between access for commercial and other purposes and creates a system for contracts between nationals and foreigners seeking access to genetic and biochemical resources within Costa Rica. However, the regulation is unclear regarding to its scope.

Several issues remain to be clarified and resolved regarding the new legislation. As long as the rules of access are applied appropriately and facilitate successful processes, however, they will be essential to achieving objectives of the CBD in Costa Rica.

Paraguay

Legislation

Although Paraguay's laws make genetic resources the property of the owner of the land they are on, the state may restrict their traffic. The state oversees and carries out phytosanitary control, qualifies and registers the lands, regulates fisheries and aquaculture, promotes forestry, and may also restrict property rights in protected areas under private domain.

Access to *ex situ* collections is free. Although the majority of materials within Paraguay's botanical collections have been taken from the country, it is also presumed that a significant number of Paraguay's species have not yet been identified. But Paraguay has already lost 80% of its forests to deforestation. It has promulgated an environmental-crimes law to protect against further environmental destruction. The efficiency of this tool will depend on the development of the administrative technical norms needed to implement it. Without these, the new law may become nothing but a decorative formula.

Although Paraguay has comprehensive environmental legislation on protected areas and wildlife, it has no specific legislation to regulate access to genetic resources in these areas. Furthermore, no regulations protect indigenous property rights to genetic resources. Paraguay also lacks legislation on many other environmental issues, including land-use planning and zoning, categorization of water use, and access to genetic resources. In addition, Paraguay has yet to develop significant jurisprudence or a national legal doctrine concerning environmental issues.

Terrestrial protected areas

Currently, only 4.4% of Paraguay's territory is protected. Many experts consider this insufficient to achieve an effective preservation of the country's wild species and ecosystems. Most of these areas also do not have the infrastructure or personnel to reach this objective. The National System of Wildlife Protected Areas is intended to cover 9.8% of the total surface area of the country. Any landowner in Paraguay may register his or her land as a protected area. This right stems from the definition of private property and the social function the law grants to land property.

Forestry patrimony

Without establishing protected areas in the technical sense of Law No. 352/94, the Forestry Law establishes special protection for wooded lands and lands suitable for forestry. The forest patrimony of the state is under the administrative jurisdiction of the National Forest Service, and this patrimony extends to the fiscal forest lands, woods, and nurseries. Notwithstanding this legal protection, Paraguay has, as already mentioned, lost 80% of its forests to deforestation. The rate at which deforestation is depleting species and the genetic resources contained in them is alarming.

Local and indigenous communities

Most of the 17 indigenous communities in Paraguay have lost their ancestral lands. These communities lack any documentation to demonstrate their ownership of these lands. The communities never asked for such recognition because they thought it unnecessary. The

state transferred these lands, together with the rest of the country's land patrimony.

The pressure on the indigenous peoples of Paraguay to maintain some of their remaining lands, recover others, and obtain new property became strongly apparent during the 1960s. During this decade, agricultural territory started to expand in Paraguay, when international credits were granted for agricultural development to exploit harvest rents, diminishing and impoverishing the existing indigenous lands.

Marine areas

Paraguay is a landlocked country and possesses no maritime territory. Consequently, it does not have national legislation on a territorial sea or continental shelf. Nevertheless, it ratified the United Nations Convention on the Law of the Sea (in Montego Bay, in 1982) through Law No. 1.195/87. Article 69 of this convention establishes the right of landlocked states to equitably exploit an appropriate surplus of living resources of coastal states in the same region or subregion, with due consideration of the economic and geographic circumstances of the affected states and the other provisions of the convention.

***Ex situ* collections**

Paraguay currently has three herbaria, in addition to scientific collections (germplasm banks, seed banks, etc.). Specific legal restrictions govern access to information on these collections or copies of the collected materials. Requests for information or copies of the materials are to be made to the authority responsible for the collection. Formation of new collections is restricted under Law No. 96/92, "Of Wildlife." Notwithstanding this, weaknesses in enforcement have facilitated uncontrolled collection and traffic of materials internationally. Most of the resources in Paraguay's botanical collections have been taken from the country.

Environmental policy

Some of the main causes of Paraguay's difficulties and failures in the enforcement of environmental law can be easily identified. None of these should be considered the main reason, as they are all

interrelated and reinforce each other. These causes include Paraguay's developing economic policy, institutional weaknesses, legislative gaps and inconsistencies, limited technical norms, lack of monetary resources, and cultural and informational weaknesses.

As a matter of policy, the government prefers not to impose requirements to mitigate the negative environmental impacts of the use or development of natural resources. Any restrictive legislation is generally sidelined to facilitate investment and economic growth.

Institutional weaknesses often appear in the incapacity of public bodies to undertake their duties proactively. They fail in their efforts to protect natural resources and the environment because of limited political commitment, a lack of technical and human resources, and unclear and conflicting responsibilities among public natural-resource management and regulative institutions. Currently, the organization of environmental institutions in Paraguay is characterized by organic diffusion.

For all these reasons, Paraguay's enforcement of its environmental legislation falls short of its aims. All these factors must be considered if Paraguay is to appropriately address issues of access and compensation for genetic resources.

Peru

Since the CBD came into force in Peru, in December 1993, the issue of access to genetic resources has been a high-priority item in discussions of the policy and legislative agenda of Peru and the South American region. Around this time — and even previously — Peru and other countries in the region were under increasing pressure from companies, universities, and research institutions to provide access to South America's rich biodiversity.

The CBD set out to establish, among other things, a basic framework of principles to develop national policies on access and compensation for genetic resources. However, the political and ideological debates surrounding this issue, in addition to the historic and legitimate claims of countries in the region regarding previous, uncompensated use of these resources for industrial and commercial purposes, have become important factors shaping national policies, laws, and regulations. If we add to this situation the potential impact

of IPR regimes over biological materials on indigenous peoples' rights regarding their knowledge of these resources, then the confrontational nature of this "North vs. South" debate becomes even more apparent.

The history of the region's access legislation clearly reflects this conflict. In July 1996, the Andean Pact countries (Bolivia, Colombia, Ecuador, Peru, and Venezuela) adopted Decision 391, a Common Regime on Access to Genetic Resources. This was an obviously defensive reaction in the context of an ongoing, convoluted, and complex debate about this issue. During initial governmental negotiations in late 1994, Peru voiced support for objective and dispassionate debate and analysis of the potential benefits of genetic resources in the region and the means to realize these benefits. Rather than promoting a strict state-controlled access system, Peru pressed for a more flexible regime allowing for cooperative arrangements within a general legal framework.

As the study of Peru pointed out, Decision 391 is a technically and procedurally complex law (which will have a bearing on the effectiveness of its implementation) and is ultimately based on the general position that the flow of resources should be strictly controlled. It establishes the key elements of an administrative framework to regulate access in the member states. Under this framework, a national authority is responsible for receiving and processing access applications. This authority is responsible for negotiating a contract with the applicant to govern terms of access. The minimum conditions on terms of access are set out in Decision 391. In addition, the applicant is usually required to enter into contracts with the providers of the biological resources and those who provide any relevant traditional indigenous knowledge concerning the resource. *Ex situ* conservation and research institutions must also sign access contracts before carrying out their collecting activities.

Before the adoption of Decision 391, the Ministry of Agriculture and Instituto Nacional de Defensa de la Propiedad Intelectual (INDECOPI, national institute for the protection of intellectual property), the national patent and completion office, established a multidisciplinary working group to assess alternatives for implementing an access regime in Peru. This group's goal was to develop a national proposal on the issue more feasible than Decision 391 and better able to serve the national interest. This group recognized the advantages

of a regional approach to regulating access but was also aware of the potential difficulties with Decision 391.

Once Decision 391 was adopted, the issue of access became a priority in the work of the National Biodiversity Commission (led by the National Environmental Council) and the national Congress. Each drafted a proposal suggesting ways and means of implementing the decision. The lack of political commitment was not as much an obstacle to effective development and implementation of the decision as the competition among various parties wishing to direct the process. It was difficult to coordinate and streamline the various efforts, which were all being made at the same time.

An interesting additional element at that time was the Government of Peru's declaration that, for political and economic reasons, it would withdraw from the Andean Pact. This generated doubts about whether Decision 391 would remain in force after Peru withdrew from the pact. However, this provided an interesting opportunity to continue exploring alternative national regulations and to strengthen the efforts of the working group.

Various institutions participating in this working group agreed that Decision 391 should give way to a more flexible access regime. However, Peru never retired from the Andean Pact and thus Decision 391 has remained in force. A proposal put forward within the working group entailed implementing Decision 391 directly and immediately — with no specific secondary regulation — and deciding on the structure and function of a competent national authority to oversee the relevant procedures and act as an implementing agency. With time, it would be possible to address procedural difficulties and subsequent modifications at the Andean Pact level.

One of the most contentious issues discussed in the access working group has been the role of *ex situ* conservation facilities, such as the International Potato Center, and how to control their activities. As was very clearly highlighted during the governmental negotiations regarding the implementation of Decision 391, some institutions consider these facilities the main "filters" for genetic resources to leave the country. Some proposals in the working group were to control the flows of resources from these centres through material-transfer agreements, which would allow these centres to continue to carry out their regular taxonomic and basic research without any undue restrictions.

After nearly 2 years, the working group published a final draft of its proposal in the Official Gazette of Peru, on 31 May 1998, for nationwide comment. This draft clearly reflects the difficulties involved in modifying Decision 391's restrictive and detailed regulations. However, the draft proposal was also intended to offer the most flexible alternative that circumstances would allow, at least with respect to *ex situ* facilities. It is very important to acknowledge that the CBD is concerned not only with regulating access, but also with facilitating and not unduly restricting it.

Within the access debate, the issue of indigenous peoples' knowledge is also a high priority on national agendas. The references to protecting indigenous peoples' knowledge in Decision 391, the national plant breeders' protection regime and industrial property law have triggered a process to develop a *sui generis* regime to protect indigenous peoples' knowledge of biodiversity. INDECOPI is undertaking this process, which includes the activities of a multidisciplinary working group and a further consultation process with the major stakeholders, including the indigenous communities themselves. Peru recognizes the importance of indigenous knowledge to the conservation and sustainable use of biodiversity. It further acknowledges that this knowledge can in some cases reduce the costs of research and development in the agroindustrial and pharmaceutical sectors.

In July 1997, Peru's national Congress enacted the Law on the Conservation and Sustainable Utilization of Biological Resources (Law 26839). This law seeks to elaborate on, and complement, some of the general provisions of the CBD, although this law includes no specific regulations on access or benefit-sharing. This is mainly because the Congress was aware at the time of the efforts of the working group to draft legislation to implement Decision 391. It does make some specific references to indigenous peoples' rights, *ex situ* conservation, technological and scientific research, and biosafety. With respect to this latter issue, a working group, set up by the National Biodiversity Commission, is drafting a national biosafety regulation on the use of genetically modified organisms and their introduction into the environment.

Some policy and institutional issues remain to be resolved in the implementation and administration of Peru's access regime. For example, policymakers have yet to address the question of how the

existing system for issuing collection permits (pursuant to the Convention on International Trade in Endangered Species of Wild Fauna and Flora [CITES]) will fit in with the framework on access established in Decision 391. There is also the question of how the National Resource Institute in charge of CITES permits in Peru will function in relation to the new national authority, also to be established pursuant to Decision 391.

United States

The United States has not yet ratified the CBD, but US federal and state laws on natural resources define the legal regime for access and compensation for genetic resources. The patchwork of laws regulating access to genetic resources in the United States today has created a fundamentally "open" system of access to those resources. This is a system in which, in most cases, the government exercises minimal if any control over access, particularly on privately owned lands. To the extent that conservation is promoted, the focus is on natural resources, habitats, and species, rather than on genetic materials.

Terrestrial areas

In the United States, national policies to promote private rights to develop resources and the free exchange of scientific information strongly influence the rights to access and compensation for genetic resources. Access to genetic resources on lands is generally controlled by the landowner, whether a private owner or a government entity. On government lands, a permit is usually required to remove of any resources. An environmental-impact statement may be required for major actions (on either public or private land) requiring a federal permit. Otherwise, on private lands, there is little governmental interference with these rights, unless an endangered species is involved; government authorization and a permit are required to remove an endangered species.

Although most federal and state land-management agencies have the right to control access to resources on properties under their jurisdiction, such access is generally granted under laws that take no account of the special relevance of genetic resources. Compensation

to these agencies for access, where available, is moreover generally limited to fees based on actual administrative costs. Mechanisms to ensure a financial return to government, based on commercialization of genetic resources, vary widely and are absent in the case of many categories of land.

Recently, the National Park Service invoked the *Federal Technology Transfer Act* (FTTA) as the legal authority for collecting money and structuring the returns of benefits from commercial products developed in the future from bacteria in the hot springs of Yellowstone National Park. However, this strategy cannot serve as a model for other federal agencies, in part because of the legal uncertainties of applying the FTTA to research on specimens from national parks. Only some of these issues will be addressed in the legal challenges against the National Park Service in response to this use of the FTTA. Moreover, on a policy level, the use of this law is not directly linked to safeguards for biological diversity and ecological integrity, which are addressed only through the agency's other conservation-oriented legal authorities. Integration of access, use, recovery of benefits, and conservation are consequently achieved in an ad hoc manner, rather than as a matter of national policy or design. Similar issues that might arise concerning other federally owned lands, state-owned lands, or waterways are not clearly covered by any approach to controlling access or limiting it to achieve conservation ends.

On private lands, the amount of compensation may be determined by the landowner. Private rights derived from commercial development based on genetic resources are further protected by laws such as the *Plant Variety Protection Act* and laws allowing persons to patent genetically engineered life forms and novel uses of naturally occurring genetic materials. Such benefits flow to the legal owner of the novel use of genetic materials and not to the government or local communities where the resources are found.

Indian tribes generally have authority to control access to the resources on their lands, which constitute 5% of the nation. However, as a result of the relationship of trust established under the Constitution, the federal government must generally approve a formal legal contract or legal instrument to enable indigenous people to grant others access to their lands or resources. This requirement presents both an opportunity to establish benefit-sharing and an obstacle to local sovereignty over such resources.

***Ex situ* collections**

Through the National Genetic Resources Program, the federal government coordinates a substantial number of *ex situ* centres, including the National Plant Germplasm System. Although the federal government generally owns the germplasm in these centres, it operates the centres under a policy of open access, with free distribution of materials for research and development to both US citizens and foreigners. An exception to the rule of federal ownership and open access is germplasm protected under the *Plant Variety Protection Act*. In such cases, the plant breeder retains ownership.

Other centres have different policies. For example, the National Cancer Institute's Development Therapeutics Program only provides materials to qualified research organizations, subject to conditions set by a material-transfer agreement. Privately operated *ex situ* centres vary in their access policies, but most allow access for research purposes, pursuant to a material-transfer agreement.

Marine zones

Substantially different laws govern marine areas. Federal authority extends over the territorial sea (12 nautical miles [1 nautical mile = 1.852 km]), as well as over the nation's exclusive economic zone, which extends 200 miles (1 mile = 1.609 km). Unless preempted by federal law, states can regulate fisheries and other activities within their boundaries, which extend for 3 miles from the coastline. Foreign research vessels within the exclusive economic zone must conduct their activities in cooperation with the federal government.

The *Magnuson-Stevens Act* controls access to most forms of genetic resources in marine areas, which covers all forms of marine animal and plant life. Regional management plans, approved by the federal government, may regulate commercial collection of marine life. Under the Act, the federal government must authorize such use under applicable management plans for the species or alternative procedures. Most management plans, to date, concern fish and other economic species. Although scientific research is exempt under the Act, genetic prospecting for product development or market research would be subject to its controls. The Act does prohibit the federal government from charging any fees other than for administrative costs on such access, with limited exceptions, such as in Pacific insular areas.

Conservation and sustainable use of genetic resources

Two principal legal regimes govern the conservation of genetic resources in the United States. The first of these regimes comprises land-management programs. About 12% of the nation's lands are in conservation parks and refuges established by federal and state governments. Many of these were created primarily to conserve biological (and hence, genetic) resources. The federal government manages an additional 20% of US land for multiple uses requiring consideration of conservation needs. In addition, private organizations, such as Nature Conservancy, have acquired more than 4 million acres (1 acre = 0.405 ha) for the conservation of rare or threatened species.

The second regime comprises laws to protect particular species, wherever they are found. Chief among these is the *Endangered Species Act*, designed to prevent the extinction of certain species or subspecies in the United States. It prohibits any person from taking a listed species from its habitat and places special obligations on federal agencies to protect both the species and its habitat. There are also state endangered-species laws and separate federal laws protecting birds and marine mammals.

A less comprehensive set of laws regulates the sustainable use of natural resources. Government laws requiring the sustainable management of forests apply primarily to federal or state lands. Federal law does not require the sustainable use of forests on private lands, and only a few states have laws to achieve this goal. However, voluntary private organizations promote it. Laws requiring the sustainable use of animal species have tended to apply only to species subject to exploitation, as in the case of federal laws regulating the harvest of migratory waterfowl and state laws regulating game hunting and sport fishing. When markets have developed for nontraditional species, unregulated exploitation tends to occur for a number of years until laws or other measures are passed in response. This occurred, for example, when markets developed for the Pacific yew, used for taxol, and horseshoe crabs, used for lobster bait. Thus, the United States appears to formulate its laws on sustainable use largely to control existing patterns of exploitation.

Laws regarding the use of marine resources are the most consistent in the United States and require the sustainable use of any

living marine resource. In practice, however, the necessary management planning has been done primarily for species subject to traditional exploitation, although the authority exists to manage and control access to nontraditional species.

Conclusion

Current US law provides a number of mechanisms for conservation of natural resources containing genetic resources and located on publicly controlled lands and waters. Nevertheless, mechanisms focusing specifically on sustainable use, particularly of genetic resources, are significantly absent. Moreover, access to genetic resources is in no way linked to independently established conservation objectives, such as those laws of the *Federal Lands Policy Management Act* or the *National Forest Management Act*. In addition, fees paid to governments for provision of access to genetic resources are not directly allocated to programs to promote the sustainable use and conservation of the species carrying these resources. US law currently lacks specific mechanisms to enable the appropriate governmental authority to recover financial benefits from commercial development of genetic resources collected from public lands or waters, nor any provisions for sharing advances in technology or research resulting from access to genetic resources from government lands or public waters.

Measures to ensure the conservation and sustainable use of genetic resources are also lacking in US law concerning the management of private lands. Although private landowners may impose these types of measures, as a condition of access, it is up to their discretion, and current laws and policies provide no incentives for private landowners to impose such conditions. Also lacking are incentives for private landowners to channel resources from commercial development of genetic resources into conservation programs.

Only a few *ex situ* collections in the United States appear to require compliance with the benefit-sharing mechanisms of the source country. It may be appropriate to examine whether and how access and use of materials in *ex situ* collections should help support technology transfer, benefit-sharing, and conservation in the country of origin. Without either private or governmental mechanisms to ensure that *ex situ* collections comply with source-country laws on access (particularly with respect to materials already collected), these

national systems may be less effective than the CBD appears to recommend. This does not mean that the general approach of open access followed in the United States should be changed. But it does suggest that alternatives are needed to support the objectives of the CBD and those of the access regimes developed in other signatory countries.

Indigenous lands in the United States, as in many countries, present particularly complex challenges for the CBD. Federally recognized Indian tribes have authority to control access to reservation lands and may establish regimes governing access, compensation, and conservation. However, such regimes may be difficult to establish or maintain if the federal and state governments continue to take an open-access approach to regulating surrounding lands with the same or similar genetic resources. If a tribe wishes to establish an access regime generating compensation, this would in many cases undergo a federal review to ensure an adequate return to the tribe. The tribal authority may voluntarily adopt conservation requirements or the federal government may impose them as a condition on its approval of a commercial collection and exploitation agreement.

Chapter 3

A Comparative Analysis

The four tables in this chapter identify specific commonalities and differences among the participating countries, as well as an overview of how each country deals with a broad range of issues. As most laws regarding access operate in the context of conservation and laws regarding sustainable use, appropriate references are made to these broader laws.

Table 1. Legal status of genetic resources.

Private areas	Terrestrial zones		Maritime zones	Ex situ centres	
	Public areas	Indigenous lands		International centres	Ex situ collections
<p>Genetic resources are considered private property if they are not owned by the states, the provinces, or the municipalities or have been appropriated by occupation (<i>Civil Code</i>, arts. 2347 and 2527)</p> <p>Phylogenetic creations are also subject to property rights (Law 20.247; Law 24.376)</p>	<p>Provinces have domain over the natural resources in their territories (<i>Constitution</i>, art. 124)</p>	<p>The provincial assemblies or provincial legislatures may rule or give instructions on the granting of indigenous lands. However, it is the responsibility of the National Congress to enact legislation concerning property issues. If such lands are traditionally occupied, then indigenous participation in the management of the natural resources of these lands is maintained (<i>Constitution</i>, art. 75(17))</p>	<p>The state has sovereign rights over living and nonliving resources of the exclusive economic zone for exploration, exploitation, conservation, and administration purposes (Law 23, art. 968)</p>		
					<p>Living resources in the maritime zones under Argentina's sovereignty are the property of the provincial governments, which can authorize their exploitation (<i>Constitution</i>, art. 124)</p>
					<p>Indigenous property has characteristics similar to those of civil property, thus requiring many of the same social arrangements or associations established in the <i>Civil Code</i></p>

Although there are no specific regulations pertaining to genetic resources found on private lands, it is generally understood that these resources belong to the landowner	Genetic resources found on federal property belong to the federal government	Aboriginal rights (ownership over land and resources) are currently a matter of dispute in the courts. To find a treaty right to control access to resources and to contract for benefit sharing, the treaty would need to be analyzed according to the applicable rules of interpretation	International law applicable to genetic resources in maritime zones recognizes no property rights over mammals found in marine exclusive zones (territorial waters) <i>res nullius</i>	Plant and animal genetic resources found in Canada's <i>ex situ</i> collections are considered "the common heritage of humankind" and are therefore common property. Resources subject to intellectual property rights are exceptions
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There are no specific regulations regarding the genetic materials of animals; however, it is understood that the genetic material of the animal is the property of the animal's owner

Private institutions can indirectly conserve genetic resources by purchasing lands for conservation purposes

(continued)

Table 1 continued.

Terrestrial zones		Maritime zones	Ex situ centres	
Private areas	Public areas		International centres	Ex situ collections
Genetic resources and their derived products originating from Andean Pact countries are considered the goods or patrimony of the nation or of the state, depending on a country's national legislation (Decision 391, art. 6)	The most important laws regulating environmental matters, after the Political Constitution, are the <i>Natural Resources Code 1074</i> and <i>Law 99 of 1993</i>	Colombia has sovereign rights over its outer continental shelf for the exploration and exploitation of its natural resources (<i>Law 10/19/78</i>)	Ex situ genetic resources are considered part of the national patrimony, and the state is responsible for their use and conservation	Ex situ conservation of cultivated species is carried out in germplasm banks with the aid of research centres, governmental agricultural research institutes, and multinational biotechnology companies. These <i>ex situ</i> facilities are of different types: seed banks, pollen banks, clone banks, and <i>in vitro</i> conservation facilities
Genetic resources are considered public domain, regardless of the property rights pertaining to the resources in which they are found	Existing legislation covering protected areas encourages the expansion of existing knowledge of genetic resources through research overseen by the appropriate authority. The entity responsible for the protection of these areas, as	Colombia has sovereignty over its territorial sea, which extends for 12 miles (<i>Law 10/1978</i>)		<i>Law 299 (1996)</i> , indicates that botanical gardens, as examples of living plant collections organized scientifically and in conformity with national law, are able to manage herbaria and plant germplasm in gene or seed banks. They

must also carry out permanent programs of basic and applied research, as well as education programs on *in situ* and *ex situ* conservation

entity has possessed the property "in good faith"

well as their administration and management, is the Unidad Administrativa Especial del Sistema de Parques Nacionales Naturales del Ministerio del Medio Ambiente (Special Administrative Unit of the System of Natural National Parks of the Ministry of the Environment)

Colombia's exclusive economic zone extends 200 nautical miles

Territorial entities, indigenous territories among them, are managed autonomously (Constitution, arts. 286-287)

Colombia has established a Coastguard body, adopted regulations for preventing the pollution of its maritime environment, and adopted measures to regulate the use and exploitation of its maritime natural resources

The state determines the use of natural resources; on indigenous territories their use is determined with community participation

(continued)

Table 1 continued.

Terrestrial zones		Maritime zones	Ex situ centres	
Private areas	Public areas		International centres	Ex situ collections
	<p>It is clearly understood that the collective property rights of ethnic groups over their territories are fundamental rights</p>	<p>Colombia approved the Protocol for the Conservation and Management of the Marine and Coastal Protected Areas of the South-East Pacific. Signatories are to adopt measures to protect and preserve fragile or vulnerable ecosystems and ecosystems of natural or cultural value, with an emphasis on flora and fauna threatened by extinction. Studies aimed at reconstruction of the environment or reintroduction of fauna and flora are conducted as necessary</p>		

As with private property, collective property has a constitutionally defined social and ecological function

The United Nations Convention on the Law of the Seas establishes that coastal states can enact (in accordance with the convention or other international laws) policy regulating the following: conservation of the sea's living resources; prevention, reduction, and control of pollution in these areas; and scientific marine research

In Colombia's exclusive economic zone, the state has jurisdiction over the exploration, exploitation, and administration of natural resources, as well as over the conservation of natural living resources on the seabed. No private entity can obtain absolute or full jurisdictional rights over these resources

Table 1 continued.

Terrestrial zones		Maritime zones		Ex situ centres	
Private areas	Public areas	Indigenous lands		International centres	Ex situ collections
<p>The <i>Civil Code</i> establishes that a landowner is also the owner of the plants and crops that are found on that land (following a Civil Law that establishes that the accessory follows the principal). The exceptions to the owner's property rights are, for example, minerals and hydrocarbons, which are state property (Political Constitution; Mining Code)</p>	<p>On state lands, genetic and biological resources may be property of the state, autonomous institutions, or the municipalities. The most important state lands are the national parks and biological reserves (administered by the Ministry of Environment and Energy as part of the National System of Conservation Areas). Access to and use of the resources on these lands require special permits, subject to limitations (arts. 36 <i>et seq.</i> of the <i>Wildlife Conservation Law</i> and Decree 12329-A of 1981 [regarding research in National Parks])</p>	<p>Indigenous reserves and territories are community property (<i>Wildlife Conservation Law</i>, art. 2). This implies that arts. 3 and 4 of the <i>Wildlife Conservation Law</i> apply to the genetic and biological resources found on these territories. Indigenous reserves are inalienable and cannot be transferred from the possession of the indigenous communities that inhabit them (<i>Wildlife Conservation Law</i>, art. 3)</p>	<p>In accordance with art. 6 of the Costa Rican Political Constitution, the state has total and exclusive sovereignty over the air space of its territory, the territorial waters for a distance of 12 miles from the coastal line, and the outer continental shelf (in conformity with the principles of international law). The state also has special jurisdiction over the adjacent seas of its territory to a distance of 200 miles and has exclusive rights to protect, preserve, and exploit all resources and natural riches existing in these waters</p>	<p>There are no legal provisions regarding genetic resources found within international centres</p>	<p>The <i>Wildlife Conservation Law</i> regulates herbaria, captive breeding facilities, zoos, etc. However, there are no specific rules regarding access to genetic resources found in <i>in situ</i> agricultural and animal collections. If these are resources located in public institutions, they are under the public domain. If they are located in private institutions, they are under the private domain. There exist no specific laws or regulations pertaining to access and distribution of the benefits obtained from accessing these resources. Any benefit-sharing policy would have to be instituted by the party in control of the resources</p>

<p>A declaration of public interest over wild flora resources applies (Wildlife Conservation Law, art. 3)</p>	<p>The Ministry of Environment and Energy can grant contracts, rights of use, licences, concessions, or any other legal instruments established for the conservation and sustainable use of wildlife (Wildlife Conservation Law, art. 17)</p>	<p>Only indigenous peoples can build houses, cut down trees, exploit wood resources, or cultivate crops on these lands (Indigenous Law, art. 8)</p>	<p>Authorization to access marine resources is granted by the Instituto Costarricense de Pesca y Acuicultura (Costa Rican Institute of Fishing and Aquaculture) in conformity with its general authority to grant permits and licences. This institute also provides technical and scientific assistance in relation to marine, aquaculture, flora, and fauna issues</p>
<p>The production, management, industrialization, extraction, and commercialization, and use of the genetic material of wild flora and fauna and their parts, products, and subproducts are of public interest and considered part of the national patrimony (Wildlife Conservation Law, art. 4)</p>	<p>Procedures established for the collection of plants and animals and their products and subproducts for research must not run counter to the Wildlife Conservation Law and its regulations (Wildlife Conservation Law, art. 36)</p>	<p>Permits to access resources on these lands must be granted by Integral Development Associations. These associations must exist in every indigenous community and represent those communities (Indigenous Law, art. 3) by the customary mechanisms traditionally used by indigenous peoples (Indigenous Law, art. 4)</p>	<p>Marine resources located within the national limits of protected areas are part of the National System of Conservation Areas, in accordance with the Pronunciamento C. 215-95 of the Procuraduría General de la República</p>

Table 1 continued.

Terrestrial zones		Maritime zones	Ex situ centres	
Private areas	Public areas		International centres	Ex situ collections
Wildlife (animals) is considered part of the public domain (<i>Wildlife Conservation Law</i> , art. 3)	Under the provisions of the <i>Organic Environment Law</i> , the state exercises its sovereignty over the national biological diversity as part of its natural patrimony. Activities to preserve, improve, and, if possible, recover the biological diversity of the national territory are in the public interest, as are activities to ensure the sustainable use of national resources (<i>Organic Environment Law</i> , art. 46)	The provisions regarding consultation, property rights, and environmental protection in the ILO Convention 169 Concerning Indigenous and Tribal Peoples in Independent Countries are applicable on indigenous lands		
In general, the <i>Organic Environment Law</i> provides the regulatory framework pertaining to the investigation, exploitation, and commercialization of biological diversity	Wild fauna, as public domain, are property of the state (<i>Wildlife Conservation Law</i> , art. 3)			

Indigenous communities must have access to a legal regime that guarantees them productive resource rights equivalent to those of other citizens (Law 904, cap. II Del Asentamiento de las Comunidades Indígenas)

Indigenous communities have common property rights to land in a state that guarantees the conservation and development of their particular livelihoods (National Constitution, art. 64)

These lands are not divisible or transferable and are not subject to contractual warranties or rents. They are not subject to taxes. Indigenous peoples cannot be removed from their lands without their express consent (National Constitution, art. 64)

Paraguay has the right to participate, on an equal basis, in the appropriate exploitation of the "surplus" of living resources in the exclusive economic zone of the coastal states of the same region or subregion (Law 1, 195/87, which ratifies the United Nations Convention on the Law of the Seas)

Access to information about, and copies of, material deposited in these centres is not subject to specific legal restrictions. However, to obtain access, interested parties must follow the procedural protocol of the institution or authority responsible for the maintenance of the collections

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Since the entry into force of the CBD the CIP requires parties depositing samples at the centre to maintain the samples under the same condition of "deposit" as those deposited and maintained before the entry of the Convention. Thus, they must conform to the rule of open access (which does not imply free of cost)

Rural and native communities have the right to use, for subsistence purposes, resources located on their lands

Genetic resources found within wild plants or animals are public domain (*Forestry Law*, art. 1)

Genetic resources found within wild plants or animals are public domain (*Forestry Law*, art. 1)

These communities are owners of the vicuñas, guanacos, and their hybrids found on their lands. The genetic material of these species may not be exported (Law 26496)

The genetic resources of domesticated species belong to the owner of the animal or plant (*Civil Code*, art. 687). This property right is not absolute according to the specific regulations of Decision 391 related to access to genetic resources

Table 1 continued.

Terrestrial zones		Indigenous lands	Maritime zones	Ex situ centres	
Private areas	Public areas			International centres	Ex situ collections
As a general rule, the landowner is also the owner of the plants on that land (under Common Law principles)	On federal and state lands, plants and their genetic resources are the property of the respective governments	The plants, fish, and wildlife found on indigenous lands (Indian Lands) are owned by the tribes but are governed by the "trust responsibility" of the federal government. This means that the federal government must approve any sale or transaction involving resources on those lands. Federal limitations on the taking of migratory and endangered species apply	Natural resources located in the territorial sea (12 nautical miles) are under the jurisdiction of the federal government. The federal government also has sovereignty over, and the authority for administering, the resources within its exclusive economic zone (which extends seaward of the state maritime boundaries)	The federal government, through the National Genetic Resources Program, coordinates a substantial number of ex situ agencies and centres. The National Plant Germplasm System is the largest and most fully functional of these. The federal government, through these centres, is the owner of the germplasm therein but operates on a policy of open access and free distribution of these materials for R&D	The federal government, through the National Genetic Resources Program, coordinates a substantial number of ex situ agencies and centres. The National Plant Germplasm System is the largest and most fully functional of these. The federal government, through these centres, is the owner of the germplasm therein but operates on a policy of open access and free distribution of these materials for R&D
Animals, fish, birds, and other wildlife are common resources that are not owned by anyone unless they are lawfully reduced to possession. State governments have the primary responsibility	States own the beds of navigable rivers and streams, as well as those living things (vegetation, mollusks, etc.) affixed to the beds of those bodies	Indigenous peoples also have some rights to harvest wildlife, fish, and plants in specific areas not on Indian Lands. These rights were granted through official agreements between	The federal government claims authority over anadromous species throughout their range (even beyond the exclusive economic zone), except in the waters of foreign nations	An exception to the general rule of federal ownership and open access is germplasm that is from varieties protected by the Plant	An exception to the general rule of federal ownership and open access is germplasm that is from varieties protected by the Plant

Variety Protection Act. In these cases, ownership is retained by the breeder

Extensive *ex situ* collections are also maintained by the National Cancer Institute, state institutions, and private collections. Many of these organizations authorize access to their materials in accordance with MTAs

(continued)

various Indian nations and the federal government

State boundaries extend 3 geographical miles from the coastline (within the territorial sea), except on the west coast of Florida and the coast of Texas, where the state maritime boundaries extend 3 marine leagues (9 geographical miles). States can regulate fisheries and other activities within these boundaries unless preempted by federal law; they have limited authority outside these boundaries

for regulating the taking of fish and wildlife. The federal government has jurisdiction over certain migratory and endangered species

In Alaska, many indigenous lands are maintained and administered by native corporations, which enable indigenous people, as shareholders, to act as private owners of the land and its resources (43 USC 1601 *et seq.*)

Animals, fish, birds, and other wildlife are common resources that are not owned unless they are lawfully reduced to possession. State governments have the primary responsibility for regulating the taking of fish and wildlife. However, the federal government also exercises this power on federally owned lands. As with private lands, the federal government also has jurisdiction over certain migratory and endangered species

Table 1 concluded.

Terrestrial zones		Maritime zones	Ex situ centres	
Private areas	Public areas		International centres	Ex situ collections
	<p>On federal lands that are considered public domain, plants and their genetic material can be acquired by private persons or entities unless otherwise prohibited.</p> <p>On federal lands classified as protected, special permits are required to remove any material</p>			
	<p>In Alaska, certain fish and wildlife resources in conservation areas can be harvested by "rural residents" for "subsistence purposes" (16 USC 3111-3126)</p>			

Note: 1 mile = 1.6 km; 1 nautical mile = 1.85 km. CBD, Convention on Biological Diversity; CIF, International Potato Center; ILO, International Labour Organization; MTA, material-transfer agreement; R&D, research and development.

Table 2. Access to genetic resources.

Terrestrial zones	Marine zones	Ex situ centres	Indigenous lands
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Access to forestry products requires a "permit of forestry products extraction." In some provinces, exploitation of public forests can be carried out under concessions, after a public bidding process

Commercialization of the remains of hunted species (from private or official hunting grounds) is prohibited; those hunted species can be commercialized (through permits for commercial hunting) when factors such as increased population and percentages of reproduction levels allow for these sorts of activities. Hunting for scientific purposes can also be authorized (Reglementary Decree 691/81)

In Natural Reserves, the hunting, capture, and collection of flora and fauna samples for research or management purposes require the express authorization of the APN (Decree 2148/90)

The appropriation of hydrobiological resources (through fishery activities) requires authorization from the appropriate authority

(continued)

Table 2 continued.

Terrestrial zones	Marine zones	Ex situ centres	Indigenous lands
<p>To obtain access to germplasm or its derivatives located in national parks, one must comply with the following requisites of the APN: the corresponding permit from the INTA; and the commitment not to transfer the germplasm to third parties (or to subject any transfer to conditions established by the INTA and the Administration [Cooperation Convention between APN and INTA])</p>	<p>Access to genetic resources is free and without restrictions to researchers and plant breeders. This general policy can be applied to resources located <i>ex situ</i></p>	<p>Beyond wildlife legislation, municipal statutes, and Acts, most public museums, zoos, plant collections, and research facilities have very general mandates to collect, display, and exchange materials for educational and research purposes. For nongovernmental <i>ex situ</i> collections, there are no regulations requiring conservation (and therefore none requiring conservation of genetic materials). For sanitary or health reasons, there are regulations regarding imported specimens. Plant Genetic Resources of Canada is an</p>	<p>Claims over Aboriginal territories (land claims) are determined through land-claim agreements. These agreements may consider genetic resources as exploitable elements on Aboriginal territories</p>

agency created to protect, preserve, and maintain the genetic diversity of Canadian crops and economically important wild plants

The provincial governments have control over the natural resources and public lands located within their jurisdiction (*Constitution Act 1867*; *Constitution Act 1982*). Control over the natural resources in the territories of the territorial and municipal governments normally lies with the federal government

Access to resources in protected areas or national parks requires authorization for collection from the Canadian Heritage Authority. No payment is required to obtain such authorization. Research must have the principal aim of promoting conservation and must conform to general guidelines established by the authority

Under the Andean Pact, to which Colombia is a signatory, all countries have sovereign rights over their genetic resources and the products derived from them. These resources are considered national

(continued)

Table 2 continued.

Terrestrial zones	Marine zones	Ex situ centres	Indigenous lands
<p>patrimony and are inalienable and not transferable to any other entity</p> <p>The state regulates the import, export, and use of the country's genetic resources in accordance with the national interest (Constitution, art. 81)</p>	<p>Decision 391 of the Andean Pact regulates access to national genetic resources, their derivatives, and their associated intangible components</p>	<p>The Ministry of the Environment of Colombia regulates the use, management, research, import, export, distribution, and commercialization of species and genetic strains of wild fauna and flora; regulates the import, export, and commercialization of genetic material; establishes the mechanisms and procedures for monitoring and control of these resources; and claims the fees and royalties derived from the use of genetic material on behalf of the national government (Law 99/93)</p>	

Authorization can be granted for temporary use of renewable natural resources in the public domain. The duration of these permits is established in accordance with the nature of the natural resources; the availability of the resources; the need for restrictions and limitations on takings to ensure conservation of the resources, and whether the use is for private commercial research or basic, noncommercial research. The authorization may not be granted for a working period exceeding 10 years (*Natural Resources Code*, cap. III)

Authorization may also be granted for research on samples of natural resources for a period of up to 2 years. No commercialization of the collected resources is allowed under these permits (*Natural Resources Code*, cap. III)

Table 2 continued.

Terrestrial zones	Marine zones	Ex situ centres	Indigenous lands
<p>The National System of Conservation Areas is the authority in charge of granting permits for collection of flora and fauna for general research, as well as for research in national parks (<i>Wildlife Conservation Law</i> and its regulations, arts. 36 <i>et seq.</i>; Decree No. 12329-a of 1981)</p>	<p>The Costa Rican Institute for Fishing and Aquaculture is the authority responsible for granting licences and providing technical and legal advice regarding marine flora and fauna. This includes technical and legal opinions on access to genetic resources (<i>Ley de Creación del Instituto Costarricense de Pesca y Acuicultura</i>, art. 2)</p>	<p>Procedures and requirements for access to resources found in <i>ex situ</i> centres depend on the institutional policies and legal structure of each centre</p>	<p>Reserves are the property of indigenous communities. The definition of these communities includes the genetic resources found therein (<i>Indian Law</i>, art. 2). Parties interested in accessing resources on these lands must seek authorization from the Association of Integrated Indigenous Development, the traditional institutional structure of the community, or the individual owner or holder of the resource or knowledge. There are no legal provisions regarding the procedural requirements and information needed to obtain this access</p>
<p>Art. 4 of the <i>Wildlife Conservation Law</i> establishes that the Ministry of Natural Resources and Energy can grant concessions, through a public bidding procedure, to private parties on terms and conditions that contribute to the national interest</p>	<p>Marine resources located within the boundaries of protected areas are part of the National System of Conservation Areas and subject to all applicable legislation</p>		
<p>Art. 17 of the <i>Wildlife Conservation Law</i> authorizes the Ministry of</p>			

Energy and Environment to grant contracts, users' rights, concessions, or any other legal instrument for the conservation and sustainable use of wildlife

Under arts. 4 and 17 of the *Wildlife Conservation Law*, the concessions for production, management, extraction, commercialization, industrialization, and use of the genetic material of wild flora and fauna can be granted through public bidding procedures

The *Wildlife Conservation Law* and its regulations establish the requirements and information needed to grant permits for research and collection of wildlife

Under a broad interpretation of Paraguay's Political Constitution, the traffic of genetic resources and their associated technology should be regulated by law, and national interests should be protected (Constitution, art. 8)

Access to material or information located in herbaria, botanical gardens, gene banks, or other *ex situ* centres requires the presentation of an application to the person or institution responsible for the collection

In areas inhabited or settled by indigenous communities, only those communities can carry out commercial hunting activities (Law 96/92, art. 41)

(continued)

Table 2 continued.

Terrestrial zones	Marine zones	Ex situ centres	Indigenous lands
<p>The Dirección de Parques Nacionales y Vida Silvestre (Office of National Parks and Wildlife) controls and monitors the hunting, breeding, traffic, and commercialization of wildlife products (Law 422/73; Decree 11, 681/95)</p>			<p>Authorization for the collection, exploitation, exportation, and commercialization of wild flora existing on indigenous lands may be granted for the purpose of scientific study, provided these activities do not affect the activities, rights, interests, and customs of those indigenous communities (Law 96/92, art. 41)</p>
<p>In the case of seeds, the Seeds Director is responsible for ensuring the availability of biological materials of high quality</p>			
<p>The Office of National Parks and Wildlife promotes cooperative agreements with national and international organizations. It also grants permits and signs concession contracts for the use of wildlife components for educational, scientific, recreational, or economic purposes. In addition, the Office exercises the corresponding regulatory control over these agreements. It also adopts administrative measures covering any use of wildlife and their parts or products (including exportation) (Law 96/92)</p>			

Every legal person (national or foreign) that carries out scientific collection must provide a duplicate of the collected samples to the National Museum

To obtain access to genetic resources in terrestrial areas, interested parties must generally present an application to the authority in charge of those resources, enter into a contract with the provider of the genetic resources (verify the compliance of the access requirements), or enter into an access contract with the state. The authority then grants a resolution that authorizes access (Decision 391, arts. 16 *et seq.*)

The access contract must ensure that the interests of the provider of biological resources, derived product, or intangible associated knowledge of components of such resources are adequately protected (Decision 391, art. 34)

To obtain access to genetic resources found in marine areas, an interested party must present an application to the competent authority, enter into accessory contracts with the provider of the genetic resource (verify the compliance of access conditions), or enter into an access contract with the state. The competent authority then grants a resolution that authorizes access (Decision 391, arts. 16 *et seq.*)

Centres or institutions that carry out research activities can enter into "framework contracts" with *ex situ* resource providers; such contracts are a more flexible mechanism to ensure their activities can continue

As a general rule, *ex situ* centres that grant access must enter into access contracts with the competent authority (Decision 391, art. 37)

In cases where the collective knowledge of an indigenous community is used (intangible component), an accessory contract must be entered into by the community and the interested party (Decision 391, art. 35)

To access resources located on indigenous lands, authorization must be sought from the community (ILO Convention 169, art. 15(2))

(continued)

Table 2 continued.

Terrestrial zones	Marine zones	Ex situ centres	Indigenous lands
<p>Decision 391 establishes minimum conditions for obtaining access that must be complied with. These include participation of nationals in research activities; strengthening of technology-transfer mechanisms; and strengthening of national institutional capacities</p>		<p>To obtain resources located in the CIP, interested parties must present an application to the centre and, in the case of designated material, the applicant is required to not seek intellectual property rights on the accessed material and to make sure that further transfer of the material is subject to the same rules</p>	
		<p>To access new material in any member country of the Andean Pact, CIP can enter into framework agreements with the competent authority of each country (Decision 391, art. 39)</p>	
		<p>To access materials located in herbaria and captive breeding facilities, an interested party must comply with the administrative requirements of each facility and usually must purchase the material</p>	

Access to resources located on lands owned by the federal government is governed by regulations, permits, or leases and is subject to conditions. Where an activity may significantly affect the environment, an EIA must be prepared	For collecting materials in the waters, seabed, or subsoil under federal jurisdiction, an EIA may be required, depending on the scope of the activity and its potential environmental impacts	Genetic materials deposited in centres that are part of the National Genetic Resources Program can be accessed by a simple written request (except for the samples of plant varieties deposited by plant breeders under the <i>Plant Variety Protection Act</i>). By law, genetic material for research purposes must be provided free of cost to both citizens and foreigners	Federally recognized Indian tribes have the authority to control access to their lands. However, when privately owned non-Indian lands are interspersed with Indian lands, their control is limited
In national parks, genetic resources can be accessed for research if a permit is obtained from the National Park Service, provided that the park is unimpaired by the activities involved in acquiring access	Although there is an exemption from regulation for scientific research conducted by a scientific research vessel, the exemption does not apply where the activity will capture and land quantities of organisms for product development, market research, or public display. These activities must be conducted under "exempted fishing procedures" and require a federal permit	When indigenous peoples grant access to their lands or resources through a formal contract or legal instrument, the Federal Department of the Interior must review and approve such agreements	
In wilderness areas, access to genetic resources and other resources is highly restricted; access must be compatible with maintaining the undisturbed character of	Research by foreign vessels may be carried out only with the full cooperation of the US government	The Plant Introduction Office handles management and shipment of foreign-exchange samples and secures the necessary phytosanitary permits	Indigenous peoples have access to certain living resources not on Indian lands through the terms of treaties with the federal government. Although the treaty rights

(continued)

Table 2 concluded.

Terrestrial zones	Marine zones	Ex situ centres	Indigenous lands
<p>these areas. Research is allowed within these areas with necessary permits</p> <p>The Bureau of Land Management has broader discretion to grant access on public domain lands through permits, leases, or easements, provided that there is not undue or unnecessary degradation of the lands. Similar permit requirements apply to national forests administered by the US Forest Service</p> <p>The US Fish and Wildlife Service may grant permits for activities, presumably including the collection of genetic resources, in national wildlife refuges</p>	<p>A federal permit is required for the taking or importation of a marine mammal for scientific research</p> <p>A federal special-use permit is required for conducting scientific research activities in marine sanctuaries</p>	<p>Microorganisms deposited in collections of the Agricultural Research Service can be freely accessed by written request</p> <p>The materials maintained by NCI's Developmental Therapeutics Program will only be provided to "qualified research organizations" subject to availability, and then only if their distribution will not adversely affect NCI programs.</p> <p>These materials are usually transferred under conditions established in MTAs, under which the NCI maintains ownership of the samples and the recipient reports on use of the samples and research results</p>	<p>themselves cannot be transferred to nonindigenous people, the materials harvested under such rights may be sold to others</p> <p>Alaskan native corporations control access to their lands and resources in the same manner as any private owner</p>

Access to resources on state-owned lands is regulated by the provisions of state laws, which vary from state to state. Some lands may be off limits, whereas others may be leased or accessible with a permit. Approximately 15 states may require EIAs, in addition to permits, before activities may be conducted on state-owned lands.

Private landowners may grant access to resources on their lands and waters

Federally recognized Indian tribes may grant access to resources on their lands and waters, subject to approval by the federal government

The federal *Endangered Species Act*, and similar state laws, and federal and state wildlife laws may prohibit or significantly limit access to certain species wherever they may be located. The US Fish and Wildlife Service can issue permits for the taking of a limited number of threatened or endangered species for scientific purposes

A state may regulate activities conducted within its coastal zone. States also may lease their seabeds and portions thereof

Private collections grant access to their materials in a variety of ways, including utilization of MTAs. Some collections offer open access, whereas others are more strictly controlled or proprietary

Note: APN, National Parks Administration; CIP, International Poroto Center; EIA, environmental-impact assessment; ILO, International Labour Organization; INTA, Instituto Nacional de Tecnología Agropecuaria (national institute for agropecuarian technology); MTA, material-transfer agreement; NCI, National Cancer Institute.

Table 3. Participation in the benefits derived from access.

Technology transfer	Participation in research or bioprospecting activities	Participation in the results of the research	Capacity-building	Rights and financial benefits
At the national level, specific regulations refer to the transfer of technology in general. These rules could be applicable to technology associated with the use of genetic diversity (Law 22.426; Law 23.877; Decree 1797/94)	Specific laws at the national and provincial levels are referred to in international treaties (multilateral and bilateral) signed by Argentina. These treaties, in turn, mention the participation of nationals in research activities. In some cases, these laws could be applied to genetic-diversity research (Law 20645; Law 23.918; Law 24.375)	At the national and provincial levels, especially regarding applicable international treaties, the participation in the results of field activities and investigation comprises can be invoked (Law 24.3375)	With regard to capacity-building associated with access to genetic resources, only the general provisions of the CBD are applicable (Law 24.375)	The general provisions of the CBD regarding matters related to the use of genetic resources and compensation for that use are applicable

At the provincial level, some provinces (for example, Córdoba) regulate the transfer of technology and the distribution of benefits arising from access to this technology. The provincial authority is entitled to regulate the use of technologies applied to natural resources (Constitution of the Province of Córdoba)

Colombia promotes the identification of technologies relevant for the conservation and sustainable use of continental, coastal, and island biodiversity

All foreign, natural, or legal persons authorized to access national genetic resources for scientific purposes are obliged to have national researchers, proposed by national entities, participate on an equitable basis on their working teams (*Natural Resources Code*, ch. 3)

Colombia will establish the mechanisms to facilitate access by research entities to technologies that facilitate the generation and promotion of knowledge related to genetic resources

Decision 391 establishes that a national institution will participate in bioprospecting activities carried out within the access to genetic-resources agreement (Decision 391, definition of "national support institution")

Colombia promotes research for the development and adaptation of technologies for production systems that support the sustainable use of the components of biological diversity

The Instituto Nacional de Asuntos Indígenas (National

Table 3 continued.

Technology transfer	Participation in research or bioprospecting activities	Participation in the results of the research	Capacity-building	Rights and financial benefits
Institute of Indigenous Matters) designs and delivers health and sanitation programs that make use of indigenous traditional medicinal knowledge, implying a form of technology (know-how) transfer (Decree 155/89)				
Art. 50 of Costa Rica's <i>Wildlife Conservation Law</i> establishes that all R&D activities performed to obtain new varieties, hybrids, pharmaceuticals, or any other product obtained from wild species and their products or subproducts must have the authorization of the Wildlife Office of the Ministry of Natural Resources, Energy and Mines. This entity may not give the authorization when the application is contrary to the public interest. The Ministry can make use of the	There are no regulations regarding the participation of nationals in bioprospecting activities. There are, however, specific agreements between the INBIO and the Ministry of Natural Resources, Energy and Mines that allow national researchers to participate in research activities. These agreements also apply to contracts between INBIO and private entities	Researchers are required to present a copy of any research publications and reports to the National Library and to the Wildlife Office of the Ministry of Natural Resources, Energy and Mines (<i>Wildlife Conservation Law</i> , art. 41)	As part of the benefit-distribution schemes between the Ministry of Natural Resources, Energy and Mines and other institutions (such as INBIO), where capacity-building is considered, collaborative agreements have been signed. The <i>Wildlife Conservation Law</i> has no specific regulations on this point, but through its general provisions, these kind of agreements have been negotiated on a case-by-case basis.	The National System of Conservation Areas (National Park Services), the Wildlife Office, and the State Forest Administration are entitled to the revenues from the tariffs for authorization of access, licences, concessions, and general services they provide to facilitate access

knowledge generated thereof, with a view to programs of particular national interest

If the collected specimens are intended for foreign institutions, the Wildlife Office will require that duplicates of the specimens be left with national institutions before authorizing exportation for scientific and cultural purposes

The Organic Environmental Law states that if environmental research is conducted on state lands or facilities, with state financial assistance, or through institutions, national, or international organizations supported by the state, a copy of the final report must be submitted to the National Research Council on Science and Technology

INBIO includes clauses that establish the need to build the capacity of state personnel as part of its contracts

There is no specific regulation applicable to royalties, but some agreements signed with INBIO provided that 50% of the royalties obtained in trade agreements were to be shared with the country. The negotiations depend on each case — there are no fixed legal or political rules

(continued)

Table 3 continued.

Technology transfer	Participation in research or bioprospecting activities	Participation in the results of the research	Capacity-building	Rights and financial benefits
As general rule, the Ministry of Agriculture and Cattle is entitled to generate and transfer technologies directly or through third parties (Law 81/92)	The Ministry of Public Health and Social Welfare promotes the development of mineral resources and studies of flora and fauna relevant to public health. Research on health sciences with the financial support of other countries or foreign organizations is also promoted (Law 836/80)	Research on genetic resources developed by public entities is the property of the state. This research is available to private parties who submit an application and pay the corresponding fee, if any	With regard to genetic resources, capacity-building is a specific function of the Agriculture and Cattle Ministry and the National University of Asunción. Private institutions can also carry out capacity-building activities, but they need authorization to act as collective entities of scientific and technological research	The National Park and Wildlife Office and the National Forest Service can establish the rates, canons, tariffs, and sanctions that correspond to the provision of services and technical and scientific studies. The National Forestry Service also establishes the sale price of forest products, as well as the fees for the use of state and private forests (Law 352/94; Law 422/73)

The Office of Agricultural Research promotes the development and identification of new biological materials and farming methods and the storing of plant species of economic importance. This same office also assists technically and collaborates with official public and private entities in the generation and

application of technology
related to seed-production
activities

Peru's patent system allows for the protection of technologies, including biotechnological processes and products (Legislative Decree 823)	The state promotes the establishment and development of scientific and technological capacity-building programs, as well as research projects oriented toward the identification, registration, characterization, conservation, and sustainable use of biological-diversity components (Decision 391, art. 8)	The authority responsible for access issues can determine the institutions where the collected material (or duplicates of samples) can be deposited (Decision 391, art. 17)	Foreign institutions that carry out activities related to access to genetic resources can cooperate in research efforts in Peru (Decision 391, art. 17)	Access contracts must establish the conditions and terms of access to genetic resources, their derivatives, and, if it is the case, the intangible components of those resources (Decision 391, art. 1)
The state promotes the use of traditional technologies (autocomas) that are ecologically adequate (<i>Environmental Code</i> , art. 29)	National institutions or persons can participate in research activities pertaining to genetic resources and their products or intangible components (Decision 391, art. 17)	The authority in charge must be allowed to access the final results of the research (Decision 391, art. 17)	Institutions that carry out activities related to access can help develop the capacity-building of indigenous and local communities. These activities may concern possible and alternative uses of relevant indigenous knowledge or innovations associated with the use of genetic resources (Decision 391, art. 17)	

(continued)

Table 3 continued.

Technology transfer	Participation in research or bioprospecting activities	Participation in the results of the research	Capacity-building	Rights and financial benefits
The institutions that carry out access activities should also authorize access to their information and develop exchange and programs for capacity-building (Decision 391, art. 17)				
The state promotes the wider application of traditional technologies of indigenous communities that are related to sustainable use and conservation of biodiversity				
The transfer of technology as a condition of access to genetic materials is not required by current law, but it may be provided for in contracts or agreements. MTAs, and some federal research permits, require the disclosure of research results (albeit not participation in proprietary technology or the resulting discovery)	Participation in research activities is not required by current law, but it may be provided for in contracts or agreements	Participation in the results of research is governed primarily by contract or private agreement	Capacity-building is not required by law; it may be provided for in contracts	Most federal government agencies are not authorized to collect fees and royalties beyond those necessary for the administrative expenses of particular permit programs on federal lands and waters. However, the US Forest Service and the Bureau of Land Management do have authority to require payments of fair market value for the collection

or use of various resources and potentially those including genetic resources collected on their lands. For activities in National Marine Sanctuaries, the Secretary of Commerce is also authorized to collect an amount that represents the fair market value of the use of the sanctuary and a reasonable return to the United States

States may impose charges for exploitation of resources on state lands and waters. Based on state laws, the resulting funds may have to be dedicated to fish and wildlife conservation programs or to the funding of public school systems

Contracts for the collection or use of resources on Indian lands are subject to federal governmental approval to ensure an adequate financial return to the Indian tribe

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Samples and information derived from materials collected in national parks, as well as the corresponding publications, must be made available to the public. However, this does not give the public (or the Parks Service) a legal interest in the results of the research or in any products resulting from the use of the accessed materials

Foreign research vessels in the exclusive economic zone must conduct their activities in cooperation with the US government

Table 3 continued.

Technology transfer	Participation in research or bioprospecting activities	Participation in the results of the research	Capacity-building	Rights and financial benefits
		The requirement for a permit to conduct research in marine sanctuaries may imply the basis for sharing results		Private landowners can secure benefits by entering into contracts with those who wish to access resources on their lands
				Subsistence rights allow Aboriginal Alaskans to harvest certain protected wildlife resources. These rights are nontransferable
				US law recognizes the right to obtain a utility patent on genetically engineered life forms (including plants, animals, bacteria, and fungi) and to patent novel uses of naturally occurring genetic materials isolated by the patentee. A patent will be issued only if the tests of "utility," "novelty," and "nonobviousness" are satisfied. The patent holder controls the exclusive right to use the subject of the patent and may license its use by others in return for financial or other benefits

The *Plant Patent Act* provides alternative patent rights for new asexually reproducing plants, which must be "distinctive," "novel," and "nonobvious."

The *Plant Variety Protection Act* provides ownership protection similar to patent rights for breeders of sexually reproducing plants if the new plant variety is "distinct," "uniform," and "stable." The registration of these varieties protects seeds and plant parts (although there is a farmer's exemption that allows farmers to save seeds for cropping in successive years). The holder of a registration under this law has the usual rights of licensing in return for financial or other benefits

(continued)

Table 3 concluded.

Technology transfer	Participation in research or bioprospecting activities	Participation in the results of the research	Capacity-building	Rights and financial benefits
				<p><i>Ex situ</i> collections maintained as part of the National Genetic Resources Program do not require payments or return of benefits, as they are subject to the program's regime of open access. The National Cancer Institute has developed letters of collection, which provide for the return of financial benefits to foreign countries if a drug is developed and licenced to a pharmaceutical company. Cooperative research and development agreements are the legal instruments used in determining the terms and conditions for the use of genetic resources</p>

Note: INB(O), National Institute of Biodiversity; MTA, material-transfer agreement.

Table 4. Conservation and sustainable use of genetic resources.

Natural protected areas	Funds for conservation	Phytosanitary measures	Environmental-impact studies	Protection of species	Mitigation measures
Wildlife Sanctuaries (for management and conservation) can be established through legislation on state or private lands (Decree 691/81)	The Provincial Fund for Parks, Reserves and Natural Monuments of Buenos Aires Province was established to maintain these categories of land and resources. The authority that oversees this fund obtains the necessary resources to comply with the relevant laws, develops studies, and conducts research in these areas (Law 10.907)	Obligatory phytosanitary control prevents the importation of any seed or vegetable (for example, rhizomes, bulbs, and roots) that could be carriers or hosts of agricultural plagues (Law 4.084)	At present, there is no national law requiring an EIA before the commencement of an activity or project. Sectorial EIA regulations (hydrocarbons; generation and transmission of electric energy; dams) have particular enforcement requirements	At the provincial and national levels, abundant legislation regulates the protection of species (mostly wildlife) through the creation of reserves and sanctuaries. In addition, legislation regulates the trade and hunting of those species	A party causing environmental damages is obliged to restore the affected environments. The terms of this restoration procedure are established by law. At present, however, there are no regulations pertaining to the legal responsibility for environmental damages and the subsequent obligation to restore ecosystems or affected environments (Constitution, art. 41)

The degradation of forest and forestry lands, as well as any irrational use of forestry products, is strictly prohibited (Law 13.273, art. 13)

The Forestry Fund and administrative funds for protected areas (Mendoza), among others, are mechanisms established to promote conservation efforts

The importation and introduction of live specimens, semen, embryos, larvae, and eggs that could disturb the ecological balance are strictly forbidden (Law 22.421, art. 4)

Provinces require the presentation of technical reports and, in some cases, the presentation of EIAs before the commencement of certain activities that might have a negative impact

The importation of products and subproducts of species of fauna, the hunting, possession, or trade of which is prohibited in Argentina, is forbidden. The importation of species of wild

(continued)

Table 4 continued.

Natural protected areas	Funds for conservation	Phytosanitary measures	Environmental-impact studies	Protection of species	Mitigation measures
Strict natural reserves offer the maximum guarantee for conservation of biodiversity on those lands (Decree 2148/90)			on natural reserves, wildlife refuges, or natural monuments	animals held in captivity is also forbidden (Law 22.241, art. 7)	
			In the case of public and private projects in areas administered by the National Parks Administration, the presentation of an environmental-impact statement or environmental report (<i>informe medio ambiental</i>) is required. The need for either is determined in accordance with the importance of the work and its impact on the environment. For small projects, the presentation of an environmental report is required	The introduction or trade of aquatic organisms (including mollusks, crustaceans, and fishes) for research, cultural, or production purposes requires certification by the National Fish and Aquaculture Authority (Resolution 902)	
					Importation of genetically modified organisms for research requires authorization (Resolution 656/92; 837/93)

Canada

There are numerous instruments for establishing (by public or private initiative) systems designed to protect wildlife under federal or provincial jurisdiction. National wildlife areas are established with provincial consent and promote research on and conservation of their wildlife populations (*Canadian Wildlife Act*)

General legislation consolidates federal authority over importation, exportation, transport, and possession of wildlife animals and plants and their parts and products. The plants and animals regulated under these regimes are established in the appendixes to CITES (CITES; Export and Import Permits Acts; *Customs Tariff Act*)

Abundant and varied federal legislation covers the conservation and use of wildlife, particularly migratory and transboundary species. The Ministry of Environment promotes, coordinates, develops, and implements education, research, and conservation of wildlife through various programs and policies (*Canada Wildlife Act*; *Migratory Birds Convention Act*)

The System of National Parks is a conservation mechanism establishing natural areas on which wildlife is protected. Furthermore, this system includes marine conservation areas that may be included in the *Canadian Wildlife Act* for the protection and conservation of marine biodiversity

Phytosanitary measures (such as quarantines) apply to international trade of wild species. Specific regulations deal with illness and pest reports (International Plant Protection Convention)

Several federal and provincial policies refer to wildlife conservation (including invertebrates, plants, microorganisms, fishes, reptiles, mammals, and their habitats) (Wildlife Policy for Canada)

Table 4 continued.

Natural protected areas	Funds for conservation	Phytosanitary measures	Environmental-impact studies	Protection of species	Mitigation measures
<p>There is legislation regulating fishery activities — maintaining stocks and prohibiting activities that negatively affect the marine ecosystem (<i>Fisheries Act</i>)</p> <p>Canada (through the Canadian Standards Association and the Canadian Council of Forest Ministers) uses indicators of and standards for sustainable forest activity</p>					
Colombia					
<p>The state is obliged to protect national environmental diversity and integrity and to conserve certain special ecological areas (Constitution, art. 72)</p>		<p>The <i>Sanitary Code</i> regulates the importation of domestic flora and fauna</p>	<p>Methodologies are in place to determine the economic costs of degradation of the environment and, in particular, of renewable natural resources (Law 99/93)</p>	<p>Protection of species through the improvement and promotion of gene banks and biotechnology programs is required. These banks are meant to facilitate research and biodiversity transfer and to</p>	<p>The proposed National Biodiversity Strategy for Colombia makes the following recommendations:</p> <ol style="list-style-type: none"> 1. Develop specific rules to protect coastal marine and submarine areas, including

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| establish clear legislation for access and exchange of information and samples | the flora and fauna found therein |
| | 2. For the conservation of biodiversity in maritime zones over which there is no jurisdiction, develop legal arguments for the establishment of an additional protocol to the CBD |
| | 3. Elaborate codes of conduct and specific legal procedures for activities that endanger or affect biodiversity conservation, for the collection and transport of marine and land species, and for <i>ex situ</i> conservation |
| | 4. Develop regulations for the introduction of living terrestrial and marine organisms modified by biotechnologies that could have an impact on the environment |
| | 5. Analyze the possibilities for developing a |
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- | | |
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| An EIA that defines the prevention, correction, compensation, and mitigation measures pertaining to the negative impacts of a particular project is required before an environmental licence for project development and execution | The development of public, private, and mixed research centres in the biotechnological and biochemical fields is promoted to facilitate the purchase of equipment and encourage personnel training. This is especially important |
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(continued)

Table 4 continued.

Natural protected areas	Funds for conservation	Phytosanitary measures	Environmental-impact studies	Protection of species	Mitigation measures
			may be obtained (Law 99/93)	for the development of biotechnologies based on the use and improvement of native species	proposal to protect coastal and marine biodiversity according to the United Nations Convention on the Law of the Seas and the CBD 6. Create an economic support fund for research on terrestrial and marine biodiversity

Cooperation between private sectors, research centres, and national and foreign entities will be promoted under the premise that the importation and exportation of genetic material are regulated

The International Cooperation Offices and the Judicial Office of the Ministry of the Environment will promote the

negotiation of a biosafety protocol and the necessary national legislation to control the impact of the introduction of exotic species or genetically modified varieties into Colombia's natural environment

Costa Rica

<p>The <i>Organic Environmental Law</i> establishes the following categories of protected areas: forestry reserves, protected zones, national parks, biological reserves, wildlife refuges, wetlands, and natural monuments</p>	<p>There are specific funds, such as the Forestry Fund (<i>Forestry Law</i>, art. 39), the National Park Funds (<i>National Park Service Law</i>, art. 16), and the Wildlife Fund (<i>Wildlife Conservation Law</i>, art. 11) for wildlife conservation and sustainable use</p>	<p>Phytosanitary regulations establish the state's authority to provide phytosanitary services to control national and international exchange of plants, agents for biological control, and other organisms used in agriculture (<i>Phytosanitary Law</i>, art. 5(g))</p>	<p>The <i>Organic Environmental Law</i> requires that human activities that may disturb or destroy environmental elements or generate general waste, toxins, or dangerous materials must have an environmental impact evaluation approved before the activity is carried out (art. 17)</p>	<p>The <i>Wildlife Conservation Law</i> regulates trade in species that are in endangered or threatened. Trading, extracting, hunting, fishing, possessing, accessing, or collecting these species is prohibited (<i>Wildlife Conservation Law</i>, arts. 14, 18, and 25)</p>	<p>The <i>Organic Environmental Law</i> and the Technical Environmental Secretary require mitigation measures for each environmental-impact evaluation (Technical Environmental Secretary Regulations, art. 11). No specific provisions apply to these measures to access genetic resources</p>
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Table 4 continued.

Natural protected areas	Funds for conservation	Phytosanitary measures	Environmental-impact studies	Protection of species	Mitigation measures
Except for natural monuments, all the above categories are administered by the National System of Conservation Areas of the Ministry of Natural Resources, Energy and Mines	A National Environment Fund (<i>Organic Environmental Law</i> , art. 93) implements the law and its objectives and finances the Technical Environmental Secretary	The <i>Phytosanitary Law</i> regulates the importation, exportation, research, experimentation, transportation, multiplication, industrial production, trade, and use of transgenic materials and other genetically modified organisms for agricultural use and their products therein (art. 5(q) and arts. 40 et seq.). To engage in any of these activities requires authorization from the Phytosanitary Protection Service	The Technical Environmental Secretary Regulations establish the projects that require an evaluation (Technical Environmental Secretary Regulations, arts. 20-22). Projects requiring access to genetic resources are not expressly included	Sustainable reproduction may be permitted in captive breeding facilities or herbaria (<i>Wildlife Conservation Law</i> , arts. 14, 25). Endangered species may be genetically manipulated only to increase their population (<i>Wildlife Conservation Law</i> , art. 25)	
National parks and biological reserves are state property. In the other categories, the property is private or mixed, with public controls and limitations		The resources for these funds are obtained from licenses, permits, bulletin sales, services, fines, donations, etc.	The Phytosanitary Protection Service controls the phytosanitary quality of propagation material and regulates and authorizes the importation of plants and the application, execution, and observation of phytosanitary measures for export of plants	An environmental-impact evaluation is required for the introduction of exotic species (<i>Wildlife Conservation Law</i> , art. 26)	Regulations pursuant to the <i>Wildlife Conservation Law</i> will determine and classify the species whose extraction is forbidden or limited (art. 59)

The purposes, objectives, and requirements of these areas are regulated by the *Organic Environmental Law*

The main objectives of the *Organic Environmental Law* are to conserve the representative natural environments; protect genetic diversity; ensure the sustainable use of ecosystems and their elements; promote active community participation; promote scientific research for the sustainable use and conservation of natural resources; protect and improve aquifers and river basins; and protect the natural landscapes surrounding historic and archaeological sites and centres (art. 35)

Art. 18 of the *Forestry Law* authorizes research, training, and ecotourism activities on the state's natural heritage lands. Environmental-impact evaluations may be required before permission for such activities is granted

It is generally not obligatory to present environmental-impact evaluations to access genetic resources, even though legislation is in place to ensure that collecting activities are sustainable and in accordance with the *Wildlife Conservation Law* and its regulations

Regulations of the *Wildlife Conservation Law* and other decrees establish which species are considered endangered or threatened (*Wildlife Conservation Law*, art. 59 and regulations, *Wildlife Conservation Law*, arts. 63-65)

Generally, legislation tends to limit wildlife trade, except when specimens come from registered captive breeding facilities or herbaria

(continued)

Table 4 continued.

Natural protected areas	Funds for conservation	Phyosanitary measures	Environmental-impact studies	Protection of species	Mitigation measures
<p><i>The National Park Service Law and Wildlife Conservation Law</i> regulate management categories for protected areas, such as the national parks and wildlife refuges</p> <p><i>The Forestry Law</i> establishes the need to ensure the conservation, protection, use, and industrialization of natural forests, as well as the promotion of forestry resources, according to adequate and sustainable use of renewable natural resources as a basic function of the state (<i>Forestry Law</i>, art. 1)</p> <p>Forests may be used only if they have an environmental plan, which includes the impact that various uses</p>				<p><i>The Forestry Law</i> has prohibitions pertaining to certain woody species (art. 6(c))</p> <p><i>The Forestry Law and Wildlife Conservation Law</i> have numerous regulations to ensure the sustainable use and conservation of Costa Rica's flora and fauna</p>	

of these lands could have on the environment. The State Forestry Administration can approve these plans according to sustainability criteria, fiscal concerns, and subsequent procedures that will be established in the regulations to this law (Forestry Law, art. 20)

The change of land use or the establishment of forestry plantations in areas totally covered by forests is forbidden (Forestry Law, art. 19)

Paraguay

Wild protected areas (zones, with natural or seminatural characteristics, established for the management, conservation, protection, and improvement of ecosystems and resources) can be under public or private domain (Law 352/94)	The Special Fund for Wild Protected Areas (under the public domain) functions according to the production rates, contributions, bonds, and royalties obtained from implementing the laws pertaining to wild protected areas	Phytosanitary control is the responsibility of the Plant Defense Bureau, which has the authority to establish quarantine systems, the certification of plant-derived products and subproducts, and related other services (Decree 37, 314/83)	An EIA is necessary when a public or private activity may modify the environment. These activities may include agriculture, farming, forest-product extraction, and the exploitation of native forests and wild flora and fauna (Law 294/93)	No specific authorization is required to extract individual specimens from their habitats until a final or provisional facility is established for receiving them and the transfer is authorized (Law 96/92, art. 45)
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Table 4 continued.

Natural protected areas	Funds for conservation	Phytosanitary measures	Environmental-impact studies	Protection of species	Mitigation measures
The forestry legislation objectives include the protection, conservation, renewal, and use of the national forest resources (Law 422/73)	The Forestry Fund finances the programs of the National Forestry Service. It obtains resources from the national budget and from rights, rates, fees, and other resources established under the forestry legislation (422/73)		A governmental approval or disapproval will support or invalidate, respectively, the conclusions of the EIA. This governmental approval constitutes the document needed for the developing of the corresponding activities	The Parks and Wildlife Bureau requires the presentation of scientific studies on the possible environmental impact of the introduction of exotic species of flora and fauna before authorizing their introduction (Law 96/92)	
Fiscal forestry lands, fiscal forests, and fiscal herbaria are considered the state's forest patrimony under the <i>Forestry Law</i> (Law 35494)	There is also a National Phytosanitary Protection Fund and a National Seeds Fund			The Wildlife Conservation and Protection System has as its main objective the conservation and sustainable use of wild flora and fauna, with adequate consideration for the preservation of habitats, protection of evolutive species and their genetic resources, and protection of endemic species (Law 96/92)	

The destruction of forests and forestry lands, as well as the irrational use of forestry products, is forbidden (Law 422/73)

The Wild Protected Areas National System preserves the environments of representative samples of landscapes and ecological and biogeographical regions. This is done to maintain national biological diversity and ecological processes that conserve genetic materials and restore degraded ecosystems (Law 352/94)

Natural protected areas	Peru (and the other	To control the exporta-	Environmental-impact	Development of a com-	Limits on access (in
are public domains administered by the National Institute of Natural Resources for research, protection, and management of controlled ecosystems,	Andean Pact signatories) will create and strengthen funds, or other kinds of financial mechanisms, to support benefit sharing in the context of access to	tion of genetic resources, sanitary certificates issued in connection with the exportation of biological resources must specify that the use of these resources as a	studies are required according to sectoral criteria and according to the possible impacts of the activity to be performed	mon regime (among the Andean Pact members) on biosecurity or biosafety (Seventh Transitory Disposition) is required	cases of fragile ecosystems, danger of genetic erosion, adverse effects of activities on human health, or cultural identity of populations) can be established through

(continued)

Table 4 continued.

Natural protected areas	Funds for conservation	Phytosanitary measures	Environmental-impact studies	Protection of species	Mitigation measures
resources, and other natural riches (<i>Environmental Code</i> , art. 51)	genetic resources, in accordance with their national laws (Decision 391, First Complementary Disposition)	source of genetic material is not authorized (Decision 391, Fourth Complementary Disposition)			national regulations pursuant to Andean Pact Decision 391, art. 45
The <i>Natural Protected Areas Law</i> establishes which areas fall under the scope of SINANPE and defines general objectives for these areas (Law 26834)	The National Fund of Natural Protected Areas is a trust fund that finances the conservation, protection, and management of Peru's protected areas (Decree Law 26154)	A product or subproduct of agricultural origin may enter the country only if it has a sanitary certificate issued by its country of origin (exporting country) (Supreme Decree 004-98, <i>Environmental Code</i> , art. 45)		Exotic species (Bora and fauna) that may affect the environment negatively are not allowed to enter the country (<i>Environmental Code</i> , art. 40)	The "Guidelines for the Formulation of Terms of Reference for Environmental Impact Studies in the Agricultural Sector" (Resolución Jefatural 021-95-INRENA, Mar 1995) have some elements that may be considered if EIAs are required by the authority responsible for regulating bioprospecting activities (R.J. 021-95-INRENA)
The law recognizes the SINANPE planning guidelines and the area's Director Plan and Master Plan as obligatory regulations that guide	The National Environmental Fund is a trust fund that finances plans, programs, projects, and activities related to environmental protection				

the activities carried out in these areas (Law 26834)

The fund is also used for strengthening environmental management capacities and supporting the sustainable use of natural resources and the natural heritage (Law 26793)

United States

<p>Federal conservation areas include national parks, national wildlife refuges, marine sanctuaries, and wilderness areas. These are managed primarily (or exclusively) for conservation, although research may be conducted therein by permit</p>	<p>The federal government has several funds for conservation of fish, wildlife, plants, lands, and waters. These include the Land and Water Conservation Fund, the <i>Pinnaman-Robertson Act</i>, and other revenues dedicated to land acquisition or conservation activities</p>	<p>Federal laws provide for phytosanitary measures pertaining to the importation or exportation of various species. They also establish programs to limit or reduce the accidental introduction of harmful exotic species</p>	<p>When a federal action might have a significant impact on the environment (whether terrestrial or marine), an EIA is required</p>	<p>The ESA prohibits the taking of threatened and endangered species (under most circumstances) and would require a permit to allow access to their genetic resources. The ESA provides for the development of species-recovery plans and habitat-conservation plans where an activity may result in an "incidental taking" of such species</p>
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Table 4 concluded.

Natural protected areas	Funds for conservation	Phytosanitary measures	Environmental-impact studies	Protection of species	Mitigation measures
<p>The US Forest Service manages national forests for a variety of purposes, including production and conservation. However, the service has the obligation to maintain viable populations of vertebrate species and to provide for diversity of plant and animal communities. The Bureau of Land Management manages public-domain lands for production and conservation but must prevent "unnecessary or undue degradation" of those lands</p> <p>The ESA requires the protection of endangered species on both public and private lands</p>	<p>Sources for state funds for conservation include hunting and fishing licences, voluntary contributions, and revenues from automobile licence plates</p>		<p>About a third of the states require EIAs for actions on state-owned lands and waters. In a few states, EIAs are required for private actions that need state or local permits</p>	<p>State laws protect threatened and endangered species</p>	<p>The <i>National Environmental Policy Act</i> requires the identification of mitigation measures for major federal actions significantly affecting the environment as part of the project decision-making process for the corresponding federal agency</p> <p>The regulations pertaining to implementation of the <i>Clean Water Act</i> require the mitigation of impacts on wetlands</p>

States own forests, nature preserves, parks, game lands, lakes and streams, and other lands that may be managed for conservation

Voluntary conservation of resources on private lands may result from legislation that prohibits or limits the destruction of wetlands and endangered species or from tax and financial incentives. Private landowners may also sell "conservation easements," allowing them to retain their property interest in the land but obliging them to manage it for purposes consistent with conservation

The *Marine Mammal Protection Act* prohibits the taking of marine mammals (under most circumstances) and would require a permit to allow access to their genetic resources

The ESA provides for the development of recovery plans for threatened and endangered species. It also provides for habitat-recovery plans in instances where an authorized activity may result in an "incidental taking" of some individual members of a threatened or endangered species

Note: CITES, Convention on International Trade in Endangered Species of Wild Fauna and Flora; EIA, environmental-impact assessment; ESA, *Endangered Species Act*; SINANPE, Natural Protected Areas System.

Chapter 4

Options for the Future

A workshop on access to genetic resources was held in Urubamba, Peru, 7–11 May 1997. Representatives of independent law centres from six countries of the western hemisphere met to discuss the findings of the research and analysis of their respective nations' laws on access and compensation for genetic resources. This research had been conducted under the framework of the Protecting the Biodiversity of the Americas project. Its aim was to promote the development of effective national laws and policies to protect biodiversity.

The purpose of this document is to contribute to the political and legislative processes leading to normative laws and policies on access and compensation for genetic resources. The following sections contain some of the general observations and conclusions drawn at the workshop.

General observations

Genetic resources are distributed throughout the world's regions and may make a valuable contribution to development efforts in both developed and developing countries. However, some countries, including many developing countries, have greater concentrations of these resources and thus a commensurately greater burden to bear in their conservation and sustainable use.

Unrestricted or improperly managed access to genetic resources can negatively affect the conservation of specific species and ecosystems if current activities result in an increasing or excessive use of these resources. This is particularly true in cases of genetic materials or active components that cannot readily be synthesized, leading to the permanent use of the resources *in situ*.

In the negotiations and implementation of the CBD, higher priority political and economic issues have subordinated environmental concerns. Consequently, some developed countries have tended to promote fewer or no restrictions on access to genetic resources, whereas some developing countries promote state control and economic compensation for the use of these resources. As discussed below, these positions partly coincide with the legal systems implemented by these countries within their own borders.

These political realities, together with perceived implications of the geographic and physical distribution of genetic resources, mean that the political discussions on access to genetic resources, at both governmental and nongovernmental levels, reflect a permanent tension between those who promote the control of access and those who promote more flexible methods for their access and use. This tension delays and impedes conservation efforts and, to a certain extent, the equitable sharing of conservation expenses.

In the political and legislative processes in some countries, the tendency is to overestimate the prospects for immediate economic benefit from regulating access to genetic resources. While this observation allows for the extraordinary real and potential value of such resources it also recognizes economic realities in the private marketplace, which involve the uncertainty of obtaining benefits from any given genetic resource and the high transaction costs required to implement an access regime. It is important, however, to realize as well that Southern countries have made major efforts to conserve biological diversity, as these countries have the greatest proportion of it. It is only fair that they ultimately share the economic benefits.

Differences between national systems for conservation and use

The research has shown that states have chosen diverse ways of implementing the CBD, whereas there are apparently two very different systems for establishing the role of the state and its rights over genetic resources.

In some countries, such as the United States and Canada, priority is given to the concept of private ownership of genetic resources, and the CBD is implemented in the context of a system of reasonably open access. In other countries, such as those of the Andean Pact and Central America, genetic resources are considered the property of the state, and states have elected to restrict access to genetic resources by requiring a permit or authorization from the state, as well as from the owner of the land or other resource where the genetic materials are found. The intention is then to distribute the profits between these two parties.

In a sense, Northern countries presume that open and reasonably free access to genetic resources will best serve all interests, whereas Southern countries presume that controlling access to genetic resources will best serve all interests. Although both systems are valid, their differences present difficulties in establishing common standards to regulate access, use, and eventual distribution of benefits from genetic resources.

Findings relating to national systems for access and compensation for genetic resources

Most countries lack a comprehensive strategy for conservation of their biodiversity and the mechanisms needed to effectively direct the economic or other benefits of biological diversity to programs for the conservation and sustainable use of the resource. In a few countries, the law may even prevent governmental agencies from receiving compensation for grants of access to genetic resources on government lands, preventing a direct connection between access

regimes on government lands and funding assistance for the conservation and sustainable use of the resource.

Efforts in some countries to implement the CBD have tended to link compensation for the benefits derived from genetic resources to systems restricting access to their use. Although implementing access regimes imposes challenges, such systems may play an important role in establishing clear, simple, and practical rules to ensure an adequate sharing of benefits from genetic resources. However, the research has shown that a compensation system based on access and origin may be difficult to implement, because of the difficulty and complexity of the mechanisms required. It may lead to undue restrictions on access, as a result of high transaction costs and detailed procedures.

It may be advisable to explore complementary or alternative options for ensuring compliance with the CBD's goals, based on notions other than access and origin as central elements of a compensation mechanism. For example, national, regional, or global funds might be created, using income generated from a percentage of the sale of products derived from genetic resources. This would involve distributing income to conservation or sustainable-use projects and to the governments of countries implementing the CBD.

Countries in various parts of the world have cooperation agreements and joint ventures for bioprospecting, which are not specifically subject to access regulations but support, in most respects, the general objectives of the CBD and the specific objectives of its article 15. General and flexible legal guidelines on access might be sufficient to promote these collaborative efforts.

***Ex situ* centres**

Much of the world's genetic diversity is stored in *ex situ* centres, and many of these centres operate on principles of open access to their materials. All countries depend on genetic resources in agriculture and food resources, and *ex situ* centres established for agricultural research generally have open-access policies. However, open access to genetic resources deposited and kept in *ex situ* conservation centres may diminish interest in the *in situ* conservation of these genes in their native ecosystems.

Legal systems should ensure that *ex situ* conservation complements *in situ* conservation, rather than becoming an alternative to it. In addition, laws in nations wishing to restrict access under the CBD should address and reconcile the various policies needed to do this.

Recommendations for national legal systems

Comprehensive approach

Countries should pursue a comprehensive approach in policies and norms concerning access and compensation for genetic resources, which should integrate economic and environmental goals. National legal systems should clarify the legal status of genetic resources and ensure that the nation can implement its approach to promote the goals of the CBD without negatively affecting the resource.

It is essential for nations to develop comprehensive national political strategies and policies requiring the translation of benefits from regimes governing access and use into specific actions for *in situ* conservation and sustainable use of the resource, including those benefits accruing to indigenous and local communities. In general, the research found that the tendency is for countries not to use the economic benefits from genetic resources in this way but to use them for other national purposes.

State systems to control access

A regulatory framework for access to genetic resources should include procedures for diverse resources, according to their end uses. In this respect, procedural systems should distinguish

- ✱ Resources with potential pharmaceutical use;
- ✱ Resources for use in agriculture and the food industry;
- ✱ Collection for research centres or centres for conservation *ex situ*;
- ✱ Basic research; and
- ✱ Other uses.

This approach would permit greater flexibility in accommodating the diverse goals of countries and help to promote the goals of conservation and sustainable use of genetic resources.

State systems with open access

A regulatory framework for states wishing to implement a system of open access should ensure the inclusion of adequate legal mechanisms to address the issues of conservation of endangered genetic resources and the unsustainable use of genetic resources.

Need for regional coordination

The widespread distribution of many species may make it difficult for a sole country or supplier to derive significant economic benefit from access to genetic resources. Therefore, regional and subregional access regimes would be useful to countries with common ecosystems and resources to ensure that they each share in the benefits. These regional regimes should be flexible and promote cooperative efforts. They should not create excessive control or unnecessary restrictions on access, which may divert prospectors to other sites or countries and, in any case, would be difficult to implement. Countries need mutual trust and collaboration to successfully implement a mutually beneficial access regime.

Recommendations for increasing national capacities in developing countries and technology transfer

To achieve an adequate sharing of benefits from genetic resources, stronger national abilities are needed in the following areas (among others): infrastructure, human-resource capacity, incentives for research in taxonomy, information systems, and screening abilities. Countries may usefully enhance their abilities in these fields independently of the systems they develop to derive direct economic benefits from access to genetic resources.

National policies should improve research and technical capacity and strengthen technical assistance at both national and local

levels. In addition, alternative technologies for access, use, and conservation of genetic resources should be evaluated, including access to information on the Internet or in patent offices. As well, the scientific and technical capabilities needed to implement this type of evaluation, analyze the information, and create practical uses should be strengthened. Countries should consider appropriate measures to strengthen national abilities to add value to their genetic resources, instead of simply acting as suppliers of primary products. This would be possible within the framework of a national strategy for conservation and sustainable use of biological diversity.

Recommendations for complementary legal regimes

Import regulations

Countries traditionally seeking access to genetic resources from developing countries may also consider adopting measures to promote benefit-sharing. To achieve the objectives of the CBD, countries that import genetic resources should take measures to promote the equitable distribution of the benefits from these resources. Legal regimes for access and use in countries that have traditionally been suppliers have been insufficient for this purpose.

Even if a country has not chosen to restrict access to genetic resources within its own borders, it can support the efforts of those that have done so by requiring that imports of genetic materials be obtained in compliance with the laws of the country of origin. This would help to create an atmosphere of mutual trust between importing and exporting countries.

Intellectual property

All countries — but particularly those regularly importing genetic resources — should consider adapting their IPR systems to achieve the objectives of the CBD. To grant a right, they may require evidence that the genetic materials in a product or process were acquired legally or that adequate compensation was provided to the country of origin, or both.

Indigenous and local communities

The protection of indigenous knowledge of biological diversity has become a growing priority on international and national agendas. Because traditional IPR systems are unsatisfactory (owing to the nature of indigenous knowledge), a method is needed to protect indigenous traditional knowledge of biological and genetic diversity and allow indigenous communities to share in the benefits. Thought should be given to adapting measures, such as know-how licences, trade secrets, and other intellectual property devices, to protect indigenous and local knowledge.

Nations have differing legal systems concerning indigenous peoples. Their rights should be preserved under both open- and restricted-access systems.

Appendix 1

Abbreviations and Acronyms

AAA	Asociación de Abogados Ambientalistas (association of environmentalist professionals) [Paraguay]
CBD	Convention on Biological Diversity
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
ELI	Environmental Law Institute [United States]
ESTADE	Estudios de Estructura y Administración del Estado (studies of the structure and administration of the state) [Ecuador]
FAO	Food and Agriculture Organization of the United Nations
FARN	Fundación Ambiente y Recursos Naturales (environmental and natural resources foundation) [Argentina]
FTTA	<i>Federal Technology Transfer Act</i> [United States]

GATT	General Agreement on Tariffs and Trade
INDECOPI	Instituto Nacional de Defensa de la Propriedad Intelectual (national institute for the protection of intellectual property) [Peru]
IPR	intellectual property rights
IUCN	International Union for the Conservation of Nature and Natural Resources
NRC	<i>Natural Resources Code</i> [Colombia]
SPDA	Sociedad Peruana de Derecho Ambiental (Peruvian society for environmental rights) [Peru]
WTO	World Trade Organization

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PROTECTING

Biodiversity

Within the countries of South and North America are found some of the most diverse collections of flora and fauna in the world. Colombia alone carries over 50 thousand different plant species. This precious resource, however, is quickly dwindling. Pharmaceutical and biotechnology companies are tapping America's genetic resources at an ever-increasing rate, and habitat destruction has pushed many species to extinction or to the brink of extinction.

Protecting Biodiversity addresses one of the most fundamental aspects of this important issue: the lack of adequate national laws regulating access to, and compensation for, the use of local genetic resources. This book is the first to compare such laws and policies across a range of countries in both the industrialized and developing worlds, including Argentina, Canada, Colombia, Costa Rica, Paraguay, Peru, and the United States. It also presents legal viewpoints, conclusions, and solid recommendations for future action.

Protecting Biodiversity is the newest reference book in the rapidly emerging legal field that combines environmental, intellectual property, contract, and administrative law. It will interest researchers, professors, and university students; public and private organizations involved in biotechnology, conservation, the environment, intellectual property, and related issues; government policymakers and development professionals; and indigenous peoples' organizations around the world.

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